Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 18, 2016 10:59 AM
To: Freedhoff, Michal (Markey)
Subject: Re: 14(c)(3) - pls take a look

Michal - this TA responds to your request on 14(c)(3) approaches.

The negative drafting approach seems like a much cleaner way for people to clearly express whatever their intended outcome is.

Please let me know if any questions. Thanks,
Sven

On Mar 17, 2016, at 10:24 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Pls also look at this list for 14(c)(3)(B). Some people seem to be more negative than others.

SHALL NOT

(i) Paragraph (3)(A) shall not apply to any condition of use of a chemical substance for which an exemption under section 6(g) has been granted;

(ii) Paragraph 3(A) shall not apply to information about a chemical substance for which a ban or phase-out is not established for all conditions of use, except that paragraph 3(A) shall apply to information that relates solely to the conditions of use of the chemical substance for which the ban or phase-out is established.

;

(iii) Paragraph (3)(A) shall not apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured, processed and distributed solely for export unless EPA determines that section 12(a)(1) shall not apply to the chemical substance in accordance with section 12(a)(2). ; and

(iv) Paragraph (3)(A) shall not apply to a chemical substance that is subject to a phase out until such time as the phase out is fully implemented.

SHAL.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 6:36 PM
To: Freedhoff, Michal (Markey)
Subject: Re: 14(c)(3) - pls take a look

Got it - thanks

On Mar 17, 2016, at 6:32 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

> (1) BAN OR PHASE-OUT.—(A) If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any information under this section with respect to the chemical substance shall be presumed to no longer apply, subject to subsections (g)(1) (g)(2) and (g)(3).
>
> (B) LIMITATIONS
>
> (i) Paragraph (3)(A) shall apply to any condition of use of a chemical substance for which an exemption under section 6(g) has not been granted;
>
> (ii) Paragraph (3)(A) shall apply to information about a chemical substance that relates solely to the conditions of use for which a ban or phase-out is established for bans or phase-outs of a chemical substance that are not established for all conditions of use of the chemical substance;
>
> (iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured, processed and distributed solely for export if EPA determines that section 12(a)(1) shall not apply to the chemical substance in accordance with section 12(a)(2); and
>
> (iv) Paragraph (3)(A) shall apply to a chemical substance that is subject to a phase out after such time as the phase out is fully implemented.

Michal Ilana Freedhoff, Ph.D.
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Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 11:42 AM
To: McCarthy, David
Subject: Re: Fees Langauge and TA

Dave,
Thanks for sending. Your email is our TA and accurately reflects our concerns with the house offer on fees. Is there specific language on fees beyond the house offer that you would like us to review. Thanks,
Sven

On Mar 24, 2016, at 11:26 AM, McCarthy, David <David.McCarthy@mail.house.gov> wrote:

From: Richards, Tina
Sent: Thursday, March 24, 2016 11:24 AM
To: kaiser.sven-eric@epa.gov <kaiser.sven-eric@epa.gov>
Cc: McCarthy, David; Kessler, Rick
Subject: Fwd: Fees Langauge and TA

Begin forwarded message:

> **From:** "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>
> **Date:** March 11, 2016 at 11:47:53 AM EST
> **To:** "McCarthy, David (David.McCarthy@mail.house.gov)" <David.McCarthy@mail.house.gov>, "Jerry Couri (JerryCouri@mail.house.gov)" <JerryCouri@mail.house.gov>, "Richards, Tina" <Tina.Richards@mail.house.gov>
> **Cc:** "Jackson, Ryan (Inhofe)" <Ryan_Jackson@inhofe.senate.gov>
> **Subject: FW: Fees Langauge and TA**
>
> Sorry about accidentally hitting send early. Wanted to share with you all some TA our dems got on fees that raises some concerns over whether the provision Dave pointed out yesterday would do the trick for our guys.
> Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.
> Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review

obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking. The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

From: Karakitsos, Dimitri (EPW)
Sent: Friday, March 11, 2016 11:41 AM
To: McCarthy, David (David.McCarthy@mail.house.gov); Jerry Couri (JerryCouri@mail.house.gov); Richards, Tina
Cc: Jackson, Ryan (Inhofe)
Subject: Fees Langauge and TA

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 25, 2016 12:19 PM
To: 'Cohen, Jacqueline'
Subject: RE: HEC Min TSCA TA Request on Prior Actions

Jacqueline,
This responds to your TA request on prior actions.

EPA has issued a great many significant new use rules under Section 5 (listed in 40 CFR Part 711), associated with various chemical substances, but EPA's view is that these have no preemptive effect because "they are not designed to protect against a risk of injury to health or the environment." See TSCA 18(a)(2)(B). EPA does not believe it is has issued any rule under TSCA Section 5 that has a preemptive effect under current TSCA Section 18.

TSCA Section 6 regulations codified under 40 CFR Part 747 (Certain metalworking fluids), Part 749 (Hexavalent chromium used in water treatment), Part 761 (PCBs), and Part 763 (Asbestos) are designed to protect against a risk of injury to health or the environment, associated with the particular chemical substances. Thus, they likely trigger some preemption of state law, under the terms of current TSCA Section 18.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 9:37 AM
To: 'Black, Jonathan (Tom Udall)'
Cc: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)
Subject: RE: House discussion draft
Attachments: Udall.TSCA TA on House Additions.docx

Jonathan,
The attached TA responds to your request on the House discussion draft. Please let me know if any questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, March 04, 2016 3:04 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey) ; Deveny, Adrian (Merkley)
Subject: House discussion draft

Sven, wondering if your crew could take a look at the attached House discussion draft and answer the following questions.

- Did anything in this offer address the specific concerns raised in EPA's January 20th letter? And if so, how?
- Do any of the additions raise workability or implementation concerns?
- Does the House discussion draft address the major concerns from the EPA Jan. 20th letter to ensure that safety decisions are made absent consideration of costs?
- Does the House draft ensure an affirmative safety finding for new chemicals?
- Do the changes require EPA to review substantiation for past CBI claims?
- Do the changes ensure that industry-requested chemicals will not be expedited relative to chemicals that EPA selects itself?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

- **Did anything in this offer address the specific concerns raised in EPA's January 20th letter? And if so, how?**

Yes, the offer appears to partially address certain concerns. First, the offer appears to partially address the concern that manufacturer priorities could overrun those of the Agency by confining the number of manufacturer-initiated risk evaluations to 25-50% of the total number of ongoing risk evaluations. EPA still has specific concerns on this point, as described in a later response. Second, the offer would seem to partially address the concern regarding funding by adding fee collection authority for EPA-initiated risk evaluations. However, the bill still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims.

- **Do any of the additions raise workability or implementation concerns?**

Yes. First, the additions reclassify a particular subset of industry requests under § 6(b)(3)(A)(ii) (relating to new chemical substances that have not yet been manufactured) as requests under § 5(i). This change makes these requests no longer subject to deadline adjustment under § 6(b)(5). Nor would such requests be subject to the new caps under § 6(b)(3)(C). Furthermore, EPA would not be able to collect fees for such requests if manufacture had not yet commenced (there would not yet be any manufacturer to against whom to assess risk evaluation fees under § 26(b)(1), and the authority to collect fees for the PMN review would not extend to cover voluntary risk evaluations. These provisions could create circumstances in which unfunded requests for voluntary risk evaluations overwhelm EPA's review capacity.

Second, the additions will require a very significant and resource-intensive implementation effort: (1) to sift through every CBI claim ever received under TSCA since the enactment of the statute; (2) to make a provisional adjudication of the qualifications of every claim; (3) to request and review re-substantiation packages where deemed warranted; (4) to notify all parties for which re-substantiation was inadequate, of pending release; and (5) to defend litigation arising from the required determinations. The implementation concerns raised by these provisions are rendered even more serious by the lack of funding for CBI review activities, and by the 5-7 year time frame specified for completing the specified CBI reviews, which could be enforced by deadline suits. Note that the Senate bill is considerably narrower in scope (only certain Chem ID claims), and it allows EPA to directly obligate CBI claimants to bring their claims (and re-substantiation) to EPA's attention, rather than creating the two-step process envisioned here. Note also that the Senate bill provides fee funding for these activities.

Third, specifying that alternative test protocols that avoid animal testing must be validated has the potential to significantly delay EPA's use of such protocols and divert EPA resources towards validation efforts. Validation as is currently implemented through Federal processes such as ICCVAM may not always be necessary depending on the context in which the alternative test method/data will be applied. While validation is recognized as an important process needed to accept an alternative method as a replacement for a whole animal test, there are circumstances under which alternative methods and the data derived from them may be valuable prior to completion of a full validation process. For

example, data from an alternative method may provide information or insights useful as part of a weight of evidence evaluation even when the method has not been fully validated as a replacement test.

- **Does the House discussion draft address the major concerns from the EPA Jan. 20th letter to ensure that safety decisions are made absent consideration of costs?**

Please note, as an initial matter, that EPA's letter did not articulate concerns that the House bill, as passed, would allow consideration of costs to factor into risk evaluations under section 6. In fact, EPA believes that the House bill – as passed and as modified recently - very clearly *excludes* consideration of costs from the both the risk evaluation and risk management triggering phases.

Rather, EPA's views letter pointed out potential inconsistencies in the application of the "unreasonable risk" safety standard elsewhere in the bill (in the risk management portions of section 6 and other sections of TSCA) which left ambiguity about the role of cost considerations in those contexts.

The bill does not attempt to address EPA's concerns on this point. For example, the bill does not provide an upfront safety standard definition or redefine "unreasonable risk" in each instance it appears. As such, there remains uncertainty as to what safety standard would apply for EPA actions under provisions of TSCA, outside of Section 6, that reference "unreasonable risk." The potential inconsistencies in risk management standards within Section 6 also remain (e.g., the standard for cost-effective v. non-cost effective requirements, and standards for regulating articles, replacement parts and PBTs).

- **Does the House draft ensure an affirmative safety finding for new chemicals?**

No, the new subsection 5(i) does not ensure that all new chemicals will receive an affirmative safety finding before the commencement of manufacture. It only applies if the person submitting the pre-manufacture notice for a chemical substance requests a risk evaluation of such substance. Subsection 5(i) is furthermore unnecessary to allow for this possibility. Such requests are already provided for under § 6(b)(3)(A)(ii).

- **Do the changes require EPA to review substantiation for past CBI claims?**

As described above, the changes require EPA to review all past CBI claims. EPA would then identify a particular subset of past CBI claims for which re-substantiation would be required and then EPA would request and review those re-substantiation packages.

With respect to the remaining CBI claims (i.e., those for which EPA did not require re-substantiation as an outcome of its initial review) the bill provides that such claims are automatically waived 10 years after enactment if re-substantiation is not sent to EPA by that time. The bill does not require that EPA review such re-substantiation, however.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

- **Do the changes ensure that industry-requested chemicals will not be expedited relative to chemicals that EPA selects itself?**

While the changes are in some respects helpful in addressing this issue, they do not ensure that the volume of industry-requested risk evaluations will be appropriately balanced against the volume of EPA-initiated risk evaluations. This is because:

- Section 6(b)(5)((B)(i) still appears to allow EPA to delay both EPA-initiated and industry-requested risk evaluations if the volume of industry-requested risk evaluations is excessive.
- Section 6(b)(7) still subjects the minimum number of EPA-initiated assessments to available appropriations.
- There is still no mechanism for industry fees to fund the development of risk management actions that EPA might be obligated to undertake as a consequence of industry-requested risk evaluations.
- As described above, a subset of industry-requested risk evaluations are now removed from caps and deadline adjustment (those accompanying a PMN).

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Saturday, February 20, 2016 5:58 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Last section 4 thing

Michal,
We did not consider costs in the decision to invoke 4f. Thanks,
Sven

On Feb 19, 2016, at 6:20 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Not for the weekend. The question of whether when you used 4(f) for formaldehyde, did you include cost considerations.

Thanks!

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, March 23, 2016 10:02 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA - another 6(a) alternative

Michal- It was not in response to that one. It was in response to the email at 9:56 am yesterday with three similar variants. Please let me know if any additional questions. Thanks,
Sven

On Mar 23, 2016, at 9:13 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just making sure that the note w alternatives that you sent last night was not in response to this one. Basically just want confirmation that the 2 alternatives I have pasted below both work for you and don't insert costs into anything?

(a) SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

SCOPE OF REGULATION—If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, then the Administrator shall by rule, and subject to section 18, apply one or more of the following requirements to such substance or mixture to the extent necessary [to ensure/so] that the chemical substance does not present such unreasonable risk, as determined in accordance with subsection (b)(4)(A), under the intended conditions of use. In selecting the particular requirement or requirements to be applied pursuant to this subsection, the Administrator shall, in accordance with subsection (c)(2), take into consideration costs and other factors in choosing among the requirements evaluated.

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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 22, 2016 3:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA - another 6(a) alternative
Michal,
This TA responds to the request to review a 6(a) option dealing with section 18 and (c)(2) references.

OPTION 2

(a) SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in

accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

The changes you suggest do help address the specific issue we identified in our most recent TA -- the suggestion that section 18 and 6(c)(2) are on the same footing as limitations on EPA's authority. However, it does not address our long standing point that we think the reference to section 18 in this context is unnecessary and confusing. We understand your point about addressing Geier, but we think section 18 already does that (and if it doesn't, it's hard to see how a reference to it in section 6 would). The reference to section 18 in section 6(c) of the offer indicates that EPA's *authority* to promulgate rules under section 6(c) is limited in some way by section 18, which we do not understand to be your intent. Presumably, you mean to say that the *preemptive effect* of any rules EPA promulgates under section 6(c) is subject to section 18. (And, again, we don't really see the value of making such a point in section 6, since section 18 already provides that it governs the preemptive effect of section 6 rules, and has whatever effect it has with respect to Geier.)

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 21, 2016 12:17 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: another 6(a) alternative

OPTION 2

(a) SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

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Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 3:12 PM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal,
This TA responds to your request on the alternate formulation. Explicitly tying disclosure regarding a ban or phaseout to "a request to maintain protections under subsections (g)(1) (g)(2) and (g)(3)" could be read to indicate that EPA can't make such information public until after the Agency receives a request from the company to maintain protection for the information. This seems unlikely to be the result that you intended.

We think it makes more sense to retain the general reference to (g) (1) – (3), which we would read as indicating that the procedures in (g) (1) – (3) must be followed where applicable.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 17, 2016 12:27 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Another formulation

> (1) BAN OR PHASE-OUT.—(A) If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any information under this section with respect to the chemical substance shall be presumed to no longer apply, subject to a review of a request to maintain protections under subsections (g)(1) (g)(2) and (g)(3).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 16, 2016 7:00 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it-checking along with the last one. Thanks,
Sven

On Mar 16, 2016, at 6:46 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does this work for 14(c)(3)(B)

> (B) EXCEPTIONS FROM PRESUMPTION
> (i) Paragraph (3)(A) shall not apply to any condition of use of a chemical substance for which an exemption under section 6(g) has been granted;
> (ii) For a ban or phase-out of a chemical substance that is not established for all conditions of use of the chemical substance, paragraph (3)(A) shall apply only to information about the chemical substance that relates solely to the conditions of use for which the ban or phase-out is established ;
> (iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured, processed and distributed solely for export if EPA determines that section 12(a)(1) shall not apply to the chemical substance in accordance with section 12(a)(2). [MF1]; and
> (iv) Paragraph (3)(A) shall apply to a chemical substance that is subject to a phase out at such time as the phase out is fully implemented.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 4:43 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular

document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 1:16 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

(c) Information Not Protected From Disclosure.—
(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:
(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
(i) IN GENERAL.—Subject to clause (ii)—
(I) any health and safety study that is submitted under this Act with respect to—
(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or
(bb) any chemical substance or mixture for which—
(AA) testing is required under section 4; or
(BB) a notification is required under section 5; or
(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).
(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—
(I) a process used in the manufacturing or processing of a chemical substance or mixture; or
(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.
(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:
(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).
(ii) A safety assessment developed, or a safety determination made, under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 1:13 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,
This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 10:32 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, December 03, 2015 4:26 PM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: Sen. Markey TSCA TA on Animal Testing
Attachments: Sen Markey TSCA TA on animal testing.docx

Michal – the attached document highlights the inconsistencies mentioned below. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Thursday, December 03, 2015 4:17 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on Animal Testing

Michal,
Although there were no EPA TA comments on the animal testing provisions of the latest version of the Senate bill, on earlier versions of the bill EPA pointed out inconsistent use of "vertebrate animal" and "animal". This inconsistency remains, please see our TA below.

- The animal testing provisions of section 4(c) remain inconsistent as to whether the goal is reduce animal testing or only vertebrate animal testing. For example, the overall goal seems to be to minimize use of vertebrate animals (sec 4(c)(1)), but in service of that goal EPA must encourage and facilitate use of test methods that eliminate or reduce the use of animals (sec 4(c)(1)(A)(iii)).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, December 01, 2015 2:42 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on House CBI

Thanks very much. On animal testing – just confirming that EPA has no drafting issues or concerns w implementing the as-reported provisions in S 697 beyond what you sent me?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, December 01, 2015 2:40 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on House CBI

Michal,
This follows up on your technical assistance request on the CBI provisions of the House TSCA bill. We have two TA comments on the attached version of the House bill.

- page 20 lines 14-17: this new text (amending section 14(b)(1)) would protect the confidentiality of chemical formulas, including molecular structures, in health and safety studies, which would result in the protection of specific chemical IDs. This would significantly curtail the release of chemical IDs in health and safety studies, which are releasable under current section 14 unless they reveal process information.

- page 22, lines 12-13: Section 14(c)(1)(C) requires EPA to provide notice to the submitter of impending release of information claimed as CBI, unless "a request for renewal is granted under subparagraph (B)." But subparagraph (B) does not require EPA to grant a renewal request; it merely requires that a request be submitted

I think this completes the outstanding TA requests, please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser
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202-566-2753

> **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
> **Date:** November 27, 2015 at 7:10:48 AM EST
> **To:** Nichole DiStefano <DiStefano.Nichole@epa.gov>
> **Subject: TA (good to start on this Monday)**
>
> Hi Nichole and hope you had a good holiday
>
> While I am thinking about itn, I wanted to request EPA TA on the following provisions:
>
> - animal testing in Senate bill
> - CBI provisions in both House and Senate bill

Guessing and hoping you've already done this for others and it will just be a matter of digging it out. Either way, it can definitely wait til Monday.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 25, 2016 8:50 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on partial risk evaluations

Michal- The 5 referenced partial risk evaluations were TCE, NMP, MC, ATO and HHCB. EPA found no concern for ATO (Antimony Trioxide) and HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[γ]-2-benzopyran). 1-BP is a draft risk assessment, and was not included in the count. See EPA's website on TSCA Work Plan Assessments:

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.

Please let me know if any additional questions. Thanks,

Sven

On Mar 25, 2016, at 7:51 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sorry, one last thing on this - you originally listed these chemicals as the subjects of these RES. But I thought in other TA you said there were 5. What is the 5th?

TCE, NMP, MC, and 1-BP.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 6:48 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
The attached TA responds to the request on partial risk evaluations. Please let me know if any questions.
Thanks,
Sven
Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 22, 2016 at 10:02:12 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on partial risk evaluations

Would this do it for you? I don't think a discussion about what you add below re cost considerations would be a constructive one. I am not sure that this works to address your concern re rules/deadlines though.

(3) (A) PRIOR-INITIATED EVALUATIONS[A1] .—

(i) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation or partial risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this Act[A2] .

(ii) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—
As relevant policies and procedures under this Act are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

(B) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation or partial risk evaluation, determination or rule solely because the action was completed prior to the completion of a policy or procedure established under this Act.

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, March 21, 2016 6:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,

This TA responds to your request on partial risk evaluations. Please let me know if any questions. Thanks,
Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Response: EPA has completed risk assessments for 5 chemicals under the TSCA Workplan process. Those assessments only consider risk. There is no cost consideration. 3 of the chemicals have high risk and are moving to the risk management phase. We are developing proposed rules. As required by TSCA we will balance costs and benefits (the value of risk reduction) and identify the least burdensome means to reduce the risk. We are scheduled to propose rules for these three chemicals later this year.

The risk assessments for all three of these chemicals had narrow scopes. We did not look at all uses of the chemicals as would be required under both House and Senate passed bills. We assume that if a bill passes before we finalize these rules we would need to finalize them using the new rulemaking standard in the law. But because the risk assessments were done without consideration of costs, we would not need to redo the work for the uses which have already been assessed.

The issue we are flagging is that meeting the scoping intent of either bill would require a significant amount of additional work on these three chemicals to assess the uses that were not included in our final assessments. That could delay regulation of the uses with known risks. Modification of the cost considerations would take a little time but much less as the cost considerations under the current law are more onerous than either the House or Senate bills. If the Senate or House bill passed as drafted we would likely call these three chemicals high

priority and make an argument that we can go forward with the narrower scoped regulations using the new standard. There is some legal vulnerability that we'd be prevented from doing so. Because the rulemaking deadlines in 6(c)(1) begin to run once EPA deems a chemical unsafe, EPA would be on a tighter time clock (4 years, as opposed to 3 years + 4 years) to both complete the risk evaluations AND any associated rulemakings with respect to other uses not part of the original evaluation. It is not clear to us whether those additional uses have risk. In the alternative, we could identify these three chemicals as high priority and then assess the additional uses before moving to risk management. The down side is that we would know there was risk for certain uses of these chemicals but we would be waiting to assess the remaining uses before doing any risk management.

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, March 20, 2016 11:16 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Questions on partial risk evaluations

Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Thanks - just trying to figure out what to do with this and how to draft it etc. Not a weekend thing for you guys!

M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

EPA TA – needs clarifying to ensure section 6 activities can proceed as intended
EPA TA here and below

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 22, 2016 5:12 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA request - risk finding to initiate risk evaluations under section 6

Michal,
We've already weighed in on alternative 1 and said that the "may present" finding there is a fairly low bar. Alt 2 introduces a "presents or will present" finding that may be interpreted as a higher bar. Thanks ,
Sven

On Feb 22, 2016, at 5:05 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Why? Just wanting to understand your thinking.
Alternative 1 is "may present:
Alternative 2 is "whether there exists the potential that the substance presents or will present"
Michal Ilana Freedhoff, Ph.D.
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Washington, DC 20510
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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 22, 2016 5:00 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request - risk finding to initiate risk evaluations under section 6
Michal,
Alternative 2 is the higher bar. Thanks,
Sven
From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 11, 2016 at 12:00:32 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TA request - risk finding to initiate risk evaluations under section 6

Sven
I'd like EPA's view on which formulation represents a higher bar to initiating a risk evaluation, and why. Thanks.
Michal
Alternative 1:

A) In general.—Not later than 6 months after the receipt of information under paragraph (3) for a chemical substance, the Administrator shall determine, using the process developed under paragraph (6);

"(i) whether the chemical substance may present an unreasonable risk of injury to human health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use, and shall identify such substances as high-priority substance for risk evaluation. The Administrator shall publish for public notice and comment the scope of the risk evaluation to be conducted for any such chemical substance; or

Alternative 2:

"(A) In general.—Not later than 6 months after the receipt of information under paragraph (3) for a chemical substance, the Administrator shall determine, using the process developed under paragraph (6);

"(i) whether there exists the potential that the chemical substance presents or will present an unreasonable risk of injury to human health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use, and shall identify such substances as high-priority substance for risk evaluation. The Administrator shall publish for public notice and comment the scope of the risk evaluation to be conducted for any such chemical substance;

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Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 2:09 PM
To: 'Freedhoff, Michal (Markey)'; Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: RE: Sen. Markey TSCA TA Request on 6(a) "minimum" and preemption

Michal, please see TA responding to your request on "minimum" and preemption.

Question: **(1) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.**

A question has arisen about the word "minimum". The word is there in part because of the Wyeth case in which the Supreme Court ruled that a VT failure to warn case was NOT preempted even though the manufacturer complied with an FDA labeling requirement. The court said there was no preemptive conflict between an FDA minimum label and what the VT failure to warn law required. The other issue the word "minimum' addresses is the scenario in which EPA sets a labeling requirement based on incomplete or false information and the people harmed by the chemical involving the inadequate label seek to prove that the company should have done more and knew that this was the case, and bring the complaint under state tort law – "minimum" therefore avoids a regulatory compliance defense so the court's decision is about the merits and not the preemptive effect of the federal label. Just because a company didn't HAVE to include the information on the label doesn't mean that they shouldn't have included it, and doesn't mean that they shouldn't have known that harm could have arisen from the chemical substance, and they shouldn't be able to assert preemption in order to avoid having the case heard.

But concerns with the word 'minimum' have been articulated as a belief that it means that a state could ALWAYS exceed a federal minimum labeling standard. My response to this is that section 18 governs this, not the word "minimum". If the state labeling law is grandfathered, it is grandfathered. If the label is required under a state clean air law, it is excepted from preemption. And if the state requests and receives an 18a waiver, preemption for it is waived. I don't see how the word 'minimum' changes anything about the way section 18 governs what states can do and when.

Does EPA agree with my read or am I missing something?

Answer: The *Geier* decision held that a savings clause saved state laws only from express preemption created by the statute, not from conflict preemption. Thus, state laws can be preempted, even if within the scope of a savings clause, if they conflict with the federal regulation at issue, either because compliance with both would be impossible, or because the state law would frustrate the objectives of the federal law.

It seems likely a court would hold that the section 18 savings provisions do not prevent conflict preemption from applying (although all the savings language in 18(g) might be held to override conflict preemption). If a court were to hold that the section 18 savings provisions do not prevent conflict preemption from applying, and a state enacted a more stringent requirement than a section 6 requirement, industry might well argue that EPA balanced various considerations in promulgating the rule, that congress was interested in uniformity, and that the federal requirements should therefore be viewed as ceilings. That may well be a weak argument – unless EPA's rulemaking record demonstrated some specific concern for more stringent requirements – but it's an argument that might be raised and would not be frivolous.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 22, 2016 5:15 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - 6(a) -"minimum"

> (1) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

A question has arisen about the word "minimum". The word is there in part because of the Wyeth case in which the Supreme Court ruled that a VT failure to warn case was NOT preempted even though the manufacturer complied with an FDA labeling requirement. The court said there was no preemptive conflict between an FDA minimum label and what the VT failure to warn law required. The other issue the word "minimum' addresses is the scenario in which EPA sets a labeling requirement based on incomplete or false information and the people harmed by the chemical involving the inadequate label seek to prove that the company should have done more and knew that this was the case, and bring the complaint under state tort law – "minimum" therefore avoids a regulatory compliance defense so the court's decision is about the merits and not the preemptive effect of the federal label. Just because a company didn't HAVE to include the information on the label doesn't mean that they shouldn't have included it, and doesn't mean that they shouldn't have known that harm could have arisen from the chemical substance, and they shouldn't be able to assert preemption in order to avoid having the case heard.

But concerns with the word 'minimum' have been articulated as a belief that it means that a state could ALWAYS exceed a federal minimum labeling standard. My response to this is that section 18 governs this, not the word "minimum". If the state labeling law is grandfathered, it is grandfathered. If the label is required under a state clean air law, it is excepted from preemption. And if the state requests and receives an 18a waiver, preemption for it is waived. I don't see how the word 'minimum' changes anything about the way section 18 governs what states can do and when.

Does EPA agree with my read or am I missing something?

Thanks
michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, December 02, 2015 3:03 PM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: Sen. Markey TSCA TA Request on PBT

Michal – the simple answer is that conceptually we would do it similar to the way new chemicals are reviewed now. However, under the bill, it will be a little more involved. Folks here are working now to sort it out. I expect a response tomorrow. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, December 02, 2015 2:38 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TSCA TA Request on PBT

Sorry, just checking again on this. thanks/

Michal Ilana Freedhoff, Ph.D.
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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, November 25, 2015 7:10 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on PBT

Michal, got it. Will get a response as soon as possible. Please let me know if any additional questions. Thanks,
Sven

On Nov 24, 2015, at 10:11 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 1:38 PM
To: 'Freedhoff, Michal (Markey)'; 'Black, Jonathan (Tom Udall)'; 'Deveny, Adrian (Merkley)'
Subject: RE: Sen. Markey TSCA TA request on section 8 nomenclature language

Michal – additional TA responding to the request on nomenclature.

First, we do believe we have the authority under section 8(b)(2) of current TSCA to designate new statutory mixtures.

Second, while the comments we made identified concerns with (A)(iii), we also have additional concerns with (B)(i) that we hope to get to you on Monday. The (B)(i) concerns are those that we stated we needed more time to fully articulate.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 22, 2016 6:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: Sen. Markey TSCA TA request on section 8 nomenclature language

Re statutory mixtures – does EPA currently have authority to designate new statutory mixtures? I think the intent of the language is to ensure that EPA could add new mixtures in the future and no intent to create the court argument you're fearing.

Also, are your concerns with (A)(iii) or (B)(i)? your email says the latter but your comments are on the former.

Monday shouldn't be a problem but the answer to the question on EPA authority with statutory mixtures would be helpful.

Thanks
m

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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 22, 2016 6:02 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request on section 8 nomenclature language

Michal – while understanding the TA request's urgency, given schedules and the specific technical and legal knowledge required on nomenclature, we need to hold off responding fully until Monday. We have concerns about (B)(i) and need more time to articulate them. Please let me know right away if that is a problem.

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the TSCA inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include byproducts that do not appear on the TSCA inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

Response: Although not able to fully respond yet, we have several concerns, including that the "including, without limitation" language suggests that there are unidentified statutory mixtures beyond the six, creating the possibility that a court might interpret the provision as expanding EPA's current understanding of the scope of statutory mixtures.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

Response: EPA has no concerns with the (B)(ii) language

We continue to work on this TA request, please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Sent: Monday, March 21, 2016 7:08 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: Time-sensitive on section 8

Sven

Can you pls rush the review of this redlined text to portions of section 8?

Here are the basic questions:

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the tsca inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include biproducts that do not appear on the tsca inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

I think there is a desire to get this to the House asap.

Thanks
M
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, March 02, 2016 10:32 AM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: Sen. Markey TSCA TA request on section 14 CBI Disclosure Penalties

Michal,
Responding to your followup TA request on CBI penalties.

House section 14(f) creates a prohibition on the use of CBI. Section 14(f) relates back to section 14(a): "No person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection." EPA has not identified any implementation concerns in its own history relating to the scope of the authorized uses of TSCA CBI that are listed under 14(a).

However, because the House bill would amend section 15(1) to allow for enforcement of, *inter alia*, "any requirement of this title", the use restrictions in 14(f) would be enforceable under TSCA section 15 against persons authorized to receive the information, such as states. The substantive effect of this conforming change on the enforceability against unauthorized use and disclosure of information under section 14 may not have been intentional. The potential for imposition of civil and criminal penalties may discourage states, local governments, tribes, and health and environmental professionals from requesting and using CBI for legitimate purposes, for fear of inadvertently using or disclosing the information in a manner not specified, and might be viewed as contrary to other efforts to increase transparency.

This issue could be alleviated by inserting a sentence in revised section 15 stating, "This section does not apply to the disclosure or use of information under section 2613 of this title", or similar language.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, February 26, 2016 11:30 AM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TSCA TA request on section 14 CBI Disclosure Penalties

As a follow up, isn't this language in the House bill new? Any workability or other concerns here?

(f) PROHIBITION.—No person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection, nor disclose such information to any person not authorized to receive such information.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, February 25, 2016 11:52 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 14 CBI Disclosure Penalties

Michal – Please see attached TA responding to your request on TSCA section 14 on CBI. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, February 18, 2016 4:09 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request section 14

Sven

House section 14 has a penalty provision related to disclosure of CBI.

We are trying to compare this provision with other disclosure penalty provisions that exist in other statutes administered by EPA. We are aware of EPCRA and SDWA provisions, some restrictions on the way RMP data is disclosed, etc., but probably lack a full awareness/understanding of their similarities/differences.

Could you pull the examples of other provisions that create penalties for disclosure of CBI that are included in EPA statutes and give us some basis to compare them with what is in House section 14, along with any problems/limitations/workability concerns that may have been unintended/experienced in those existing statutes? Happy to get any concerns about the way that House provision might be expected to work as well.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 10, 2016 12:43 PM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: Sen. Markey TSCA TA request- section 5 scope of preemption

Michal,
This responds to your followup question on the example of a chemical where additional risks became known later. The example we provided was TBB.
Consent order signed -- 11/5/96.
Notice of Commencement -- 6/12/97
Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
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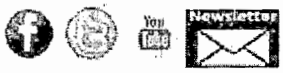
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 02, 2016 5:06 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request- section 5 scope of preemption

Thank you very much. When was that? and was that TBB or a different chemical?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, February 02, 2016 5:01 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request- section 5 scope of preemption

Michal,
This responds to your TA request below.

Are there examples of chemicals that EPA imposed some sort of restriction on (either through a PMN consent agreement with a single manufacturer or through a SNUR to all potential manufacturers of that chemical) that, after EPA obtained more data once the chemical had been in commerce for some time, turned out to pose much greater or different risks

than EPA initially believed existed at the time the first PMN was submitted/reviewed? Were any of these chemicals subsequently regulated by States once these added/new risks became known? Any and all examples are welcome – I'm trying to turn my concerns about that House provision into a real world example if one or more exist.

EPA Response:
One of the major components of the fire retardant product Firemaster 550 came through the TSCA new chemicals program before all of the concerns for this class of chemicals had become clear. EPA regulated some aspects of its use (e.g., not allowing releases to surface water) but did not address others, such as human health hazards and potential exposure, that we would now flag for further assessment and action based on more recent information.

Several states have either put restrictions on these chemicals, or have proposed to do so. For example, Minnesota enacted legislation to prohibit the manufacture, sale, offer for sale, or distribution for sale or use of children's products and furniture containing a minimum quantity of flame-retardant chemicals. California is currently reviewing flame retardants when used in furnishings or in building products, including ingredients in Firemaster 550, to investigate whether they should be subject to their Safer Consumer Product Regulations. This process in California is focused on determining if safer substitutes are available.

This technical assistance is provided in response to a congressional request and is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill language and comments. Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, January 15, 2016 1:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request- section 5 scope of preemption

Sven

I'm interested in seeing whether there are any real-world examples that could illustrate potential problems with House scope of preemption for new chemicals.

Are there examples of chemicals that EPA imposed some sort of restriction on (either through a PMN consent agreement with a single manufacturer or through a SNUR to all potential manufacturers of that chemical) that, after EPA obtained more data once the chemical had been in commerce for some time, turned out to pose much greater or different risks than EPA initially believed existed at the time the first PMN was submitted/reviewed? Were any of these chemicals subsequently regulated by States once these added/new risks became known? Any and all examples are welcome – I'm trying to turn my concerns about that House provision into a real world example if one or more exist.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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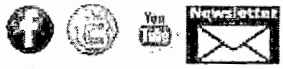
Connect with Senator Markey



Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 12:05 PM
To: 'Black, Jonathan (Tom Udall)'
Cc: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)
Subject: RE: Sen. Udall TSCA TA Request on User Fees

Jonathan,
Last year we provided to CBO that current EPA funded assessments can be up to $1 million each and current risk management actions can cost about $1.5 million each – adding up to the $2.5 million figure you asked about. At this point, we don't have any reason to change the estimates based on the various versions of the bills under consideration. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
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From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 10, 2016 9:54 AM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey) ; Deveny, Adrian (Merkley)
Subject: RE: Sen. Udall TSCA TA Request on User Fees

We have it somewhere that it costs approx. $2.5M from start to finish (on average to evaluate a chemical and then regulate it).

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, March 10, 2016 9:54 AM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Sen. Udall TSCA TA Request on User Fees

Jonathan – checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 10, 2016 9:53 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>

Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: User Fees

Sven, I'm trying to find T.A. that was already provided to me that explains the costs of risk evaluations and regulations of chemicals.

The only one I can find at the moment is this one. is there a way to track down other fee related T.A. that has been provided already?

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 17, 2016 2:49 PM
To: 'Karakitsos, Dimitri (EPW)'
Subject: RE: SEPW TSCA budget request

Dimitri – FY2016 Pres Bud request for CRRR was $56,304,000 and 239.2 FTE

See p. 485 - http://www.epa.gov/sites/production/files/2015-02/documents/epa_fy_2016_congressional_justification.pdf

Thanks,
Sven

Sven-Erik Kaiser
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From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Wednesday, February 17, 2016 1:40 PM
To: Kaiser, Sven-Erik
Subject: Re: SEPW TSCA budget request

Thanks Sven - can you just give me the fy requested for 2016 as well? Not just the enacted?

No need for a call.

From: Kaiser, Sven-Erik
Sent: Wednesday, February 17, 2016 1:33 PM
To: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA budget request

Dimitri – below are the most recent budget numbers. – See p. 502 in the Congressional Justification - http://www.epa.gov/sites/production/files/2016-02/documents/fy17-congressional-justification.pdf. Let me know if you want to discuss – today is bad but Wendy could do something first thing tomorrow morning if helpful.
Thanks,
Sven

Sven-Erik Kaiser
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Toxic Substances: Chemical Risk Review and Reduction
Program Area: Toxics Risk Review and Prevention
Goal: Ensuring the Safety of Chemicals and Preventing Pollution
Objective(s): Ensure Chemical Safety

(Dollars in Thousands)

	FY 2015 Actuals	FY 2016 Enacted	FY 2017 Pres Bud	FY 2017 Pres Bud v. FY 2016 Enacted
Environmental Program & Management	*$58,721.1*	*$58,554.0*	*$67,186.0*	*$8,632.0*
Total Budget Authority / Obligations	$58,721.1	$58,554.0	$67,186.0	$8,632.0
Total Workyears	225.1	238.7	248.7	10.0

From: "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>
Date: February 17, 2016 at 11:00:09 AM EST
To: Sven Kaiser <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TSCA budget request

Sven, I keep seeing different numbers in what you all have requested both this year and last year for TSCA (within the Chemical Risk Review and Reduction). In FY 17 for example I have seen the number $62.4 as well as $67.2. For FY 2016 I have seen both $69 million and $56.3 million.

Can you all quickly get back to me on what exactly the budget request was last year for TSCA activities (even if it is within two programs) and what it is this year?

Happy to talk with someone if it is helpful and easier to explain.

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 18, 2016 10:35 AM
To: Freedhoff, Michal (Markey)
Subject: Re: TA request - section 14(c)(1) and (2)

Michal- this I TA responds to the section 14(c)(1) and (2) request. Please let me know if any questions. Thanks, Sven

EPA's read of the Senate-passed text is that EPA has to disclose everything in health and safety studies even if parts of those studies would qualify as CBI under FOIA. As we read (c)(2), it merely provides that if protectable information is submitted along with un-protectable information, EPA must protect the former while disclosing the latter. For example, if a company submits a health and safety study along with a cover letter providing protectable process information that the company claims as CBI, (c)(1) and (2) read together require EPA to release the study and protect the letter (which, per earlier TA, EPA would do anyway).
If 14(c)(2) were read to require protection of otherwise protectable information *contained in* the health and safety study, it would drain 14(c)(1) of any force. Under this reading, 14(c)(1) would provide only that information in a health and safety study that is not protectable under the 14(a) standard is not protectable, putting health and safety studies on the same footing as any other submission.
You raise the issue of why 14(c)(1) is not already drained of force, given that 14(c)(2) is already present in the bill. Here's why not: 14(c)(2) only protects information that is already "eligible for protection under this section," and provides that eligible CBI does not lose that CBI protection simply by being juxtaposed with information that is not eligible for protection as CBI. But 14(c)(1) reflects a separate and logically prior determination that the information included in the health and safety study is not eligible for protection under this section, and thus 14(c)(2) doesn't even become relevant. However, if the 14(c)(2) proviso (that the location of the CBI won't cause a loss of CBI protection) is incorporated back into 14(c)(1), then it could have the effect of neutralizing 14(c)(1).

On Mar 17, 2016, at 6:24 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

This is a continued question about (c)(1) and (c)(2), re-pasted below.
Is EPA's read of Senate-passed text that it has to disclose everything in health and safety studies even if parts of those studies would qualify as CBI under FOIA? If so, I don't understand why, given (c)(2). If not, then why does that first "subject to para 2" change anything?
Thanks
Michal

> (a) Information Not Protected From Disclosure.—
> (1) IN GENERAL.—Notwithstanding subsections (a) and (b), [and subject to paragraph (2)],[MF1] the following information shall not be protected from disclosure:
> (A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
> (i) IN GENERAL.—Subject to clause (ii)—
> (I) any health and safety study that is submitted under this Act with respect to—
> (aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

(bb) any chemical substance or mixture for which—

(AA) testing is required under section 4; or (BB) a notification is required under section

5; or

(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (dA risk evaluation conducted under section 6.

(ii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iii) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742
Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 01, 2016 12:41 PM
To: Fruci, Jean
Subject: Re: TSCA ITC

Jean,
I'm away from my desk, will call in 30 min. Please see EPA's response to your question.

Yes, the Interagency Testing Committee (ITC) still exists and meets twice a year to review federal data needs for chemicals to add to the Priority Testing List (PTL). When the ITC makes changes to the PTL, it sends a report to the EPA Administrator, who then publishes the report for public comment. Although the ITC did meet on a semi-annual basis in 2014-15, it did not recommend any changes to the PTL. As a result, no report was published. The next ITC meeting is scheduled for March 2016.
Please let me know if any additional questions. Thanks,
Sven

On Feb 1, 2016, at 12:27 PM, "Fruci, Jean" <Jean.Fruci@mail.house.gov> wrote:

Sven:

Any progress on this? Would you give me a call, please?

Jean

Jean Fruci, Ph.D.
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515
202 225-4407
jean.fruci@mail.house.gov

-----Original Message-----
From: Fruci, Jean
Sent: Tuesday, January 26, 2016 4:50 PM
To: 'Kaiser.Sven-Erik@epa.gov' <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA ITC

Sven:

I was doing some background work on the existing ITC.

I see there are regular reports from the TSCA Interagency Testing Committee through Jan. 2014. Does the Committee still exist? Why were there no reports issued in 2015?

Thanks. I hope you are surviving the snow storm.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 2:34 PM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: TSCA TA - Section 6 Issue

Michal - are you referring to 26(j)(4)? If so, that does not address the issue.

The provision allows EPA to continue section 6 work while the policies, procedures and guidance required under the bill are being developed. But it does not address the issue of how the "partial" risk assessments or determinations that EPA is currently pursuing would fit into the new section 6 structure.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 17, 2016 2:21 PM
To: Kaiser, Sven-Erik
Subject: Re: TSCA TA - Section 6 Issue

Question - what about our section 26 language

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 2:10 PM
To: Freedhoff, Michal (Markey)
Subject: TSCA TA - Section 6 Issue

Michal,
In reviewing bill text (house and senate passed bills), EPA just discovered a technical issue that will have significant policy implications for EPA's ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA's ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments.

As you know, EPA has been working on risk assessments (draft and final) for a number of chemical substances - TCE, NMP, MC, and 1-BP. These risk assessments have been scoped relatively narrowly, so as to focus the Agency's resources on uses most likely to present risk. EPA is *not* looking at all the conditions of use for these chemicals.

This approach, which might be characterized as a *partial* risk evaluation or *partial* safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use – not just a subset of those uses.

Should the House/Senate construct become law, the Agency would be left with a difficult choice in moving forward with our ongoing Work Plan assessment and rules.

One option might be to move forward with finalizing the risk evaluation and regulating a subset of chemical uses. There's some risk that the new law would not support such an interpretation. Even if it would, the risk management deadline for the chemical would start ticking immediately. That means that EPA would be on the clock to expand the risk evaluation to cover remaining non-scoped uses, finalize those determinations, AND complete a rulemaking to manage any associated risks. For risk assessments that are draft or final, this appears to be the public policy preferred option. It's highly unlikely that EPA would be able to complete this work for non-scoped uses within the statutory timeframes.

Alternatively, EPA could hold off on moving to risk management finalizing and spend additional time evaluating the full suite of uses. This would have the practical effect of allowing known risks to health or the environment (i.e., those identified in the narrowly-scoped assessment) to continue unregulated during this period.

We'd welcome an opportunity to work with you on a drafting solution to this issue, but wanted to bring to your attention as soon as possible.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 10, 2016 6:32 PM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: URGENT FW: Sen. Markey TSCA TA - Senate section 4

Michal - If by "section 5 testing", you mean testing under the authority of section 4(a)(1)(A) to review a notice under 5(d), then the answer is YES. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 10, 2016 6:17 PM
To: Kaiser, Sven-Erik
Subject: Re: URGENT FW: Sen. Markey TSCA TA - Senate section 4

Thanks. Confirming to be sure that this applies to section 5 testing too, when there is less information available to EPA?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Wednesday, February 10, 2016 6:14 PM
To: Freedhoff, Michal (Markey)
Subject: FW: URGENT FW: Sen. Markey TSCA TA - Senate section 4

Michal,
Below is the last piece of urgent TA on Senate section 4. The other TA requests are in process. Thanks,
Sven

Someone has just proposed the following savings clause to be added to the end of section 4. I do not know whether it is truly conforming and am also not sure what it is intended to accomplish. Can you pls check it out?

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive[A1] Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act[A2] ".

EPA Response: Compared to the bill language passed out of the Senate, this proposal would raise the bar for EPA to require testing under Section 4, requiring the Agency to find both a "reasonable basis of concern about the potential risk" AND that testing is necessary for one of the specified purposes in 4(a)(1)(A)-(D). The bar for testing is still lower than current law, which requires a finding that a chemical either "may present an unreasonable risk" or has substantial volume/exposure. Moreover, EPA is finding it difficult to imagine a

scenario in which there would be such an absence of chemical data (or any other scenario) as to perpetuate the catch-22.

Sven-Erik Kaiser
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Conforming amendment that came up in discussions.
I'm not familiar with this – who brought it up?

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 10, 2016 5:20 PM
To: 'Freedhoff, Michal (Markey)'
Subject: RE: URGENT FW: Sen. Markey TSCA TA - Senate section 4

Michal – a clarification on the earlier TA below The suggested bill text refers to the 3rd sentence in the relevant provision of CERLA, but it's actually the fourth. Here's the revised proposed response, with that added.

Assuming this would be a change to the Senate bill, this seems appropriate and truly conforming. We note, though, that the proposed language indicates that it is changing the third sentence in the CERCLA provision, but the relevant language is actually in the fourth sentence.

Assuming we have that right: the provision of CERCLA that would be amended requires ATSDR, before embarking on a program of chemical testing, to "consider the recommendations of the ITC under section 4(e) of TSCA on the types of research that should be done." This amendment would add "as in effect on the day before the date of enactment of" FRL after "TSCA". This seems appropriate, because TSCA as revised by the senate bill would no longer have a provision authorizing the ITC, and the new section 4(e) would have nothing to do with the ITC.

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Michal – below is additional TA on the section 4 question. We're still working on the other question and we'll get you that as soon as possible. Thanks,
Sven

Assuming this would be a change to the Senate bill, this seems appropriate and truly conforming. The provision of CERCLA being amended requires ATSDR, before embarking on a program of chemical testing, to "consider the recommendations of the ITC under section 4(e) of TSCA on the types of research that should be done." This amendment would add "as in effect on the day before the date of enactment of" FRL after "TSCA". This seems appropriate, because TSCA as revised by the senate bill would no longer have a provision authorizing the ITC, and the new section 4(e) would have nothing to do with the ITC.

Someone has just proposed the following savings clause to be added to the end of section 4. I do not know whether it is truly conforming and am also not sure what it is intended to accomplish. Can you pls check it out?

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive[A1] Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act[A2] ".

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 10, 2016 3:39 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA - Senate section 4

Sven, it would be great to get the rest of the section 4 stuff before 4:30. Thank you.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Section 4(f) says "if EPA thinks something is super dangerous, regulate it quickly or tell everyone why there is no unreasonable risk".

Does EPA believe that it could decide not to regulate the super dangerous thing because it would be too expensive to do so, or does it believe that "unreasonable risk" is solely risk-based?

EPA Response: We believes that an unreasonable risk determination in section 4(f) of current TSCA would factor in costs as well as benefits. Such a determination would not be solely risk-based.

Do you believe that the exclusion of costs in 4(f) that I sent you in the file yesterday in this section is needed to maintain consistency with the rest of the bill?

EPA Response: We believe the exclusion-of-costs language would be important to ensure consistency with the rest of the bill.

Do you believe that, if we exclude costs as drafted in the document sent yesterday, that EPA would still be required to consider costs when developing regulatory action? If not, how would EPA draft 4(f) that 1) does not remove the words "unreasonable risk" and substitute another standard and 2) ensures that costs are considered as appropriate when regulating, but not when deciding WHETHER to regulate.

EPA Response: We believe that EPA would be required to consider costs when developing regulatory action to the extent cost consideration is required by section 5, 6 or 7 as modified by the Senate bill, even if cost is eliminated as a consideration under section 4(f). In fact, we believe the elimination of cost considerations from the unreasonable risk judgment in section 4(f) would be consistent with the usage of "unreasonable risk" in sections 5, 6 and 7. As we interpret those sections, and the definition of the safety standard in section 3, cost is not a factor in judgments about whether a risk is unreasonable. EPA must nonetheless consider cost in its risk management decisions. For example, under section 6, EPA would to consider cost and other factors in determining the most appropriate restrictions to eliminate any unreasonable risk, but the determination of whether any remaining risk is unreasonable would be made without regard to cost. In addition, under section 6, EPA could consider cost in deciding whether to issue exemptions under section 6(d)(5).

We note that sections 5 and 6 in S bill now require an affirmative finding on the part of EPA. Would one solution be to end the sentence in 4(f)(2) after "5,6 or 7" and then go to "For good cause"?

EPA Response: Per the answer to the question above, we do not see a problem with the drafting that needs to be solved. And we believe implementation issues could be created by dropping the text you suggest from section 4(f). Without that text, EPA would be required to take action under section 5, 6 or 7 for every chemical for which information "*indicates* to the Administrator that there *may be a reasonable*

***basis* to conclude that [the] chemical substance or mixture presents or will present a *significant* risk of serious or widespread harm to human beings" (emphasis added). This finding is a tentative one, and the standard – significant risk – is different from "unreasonable risk". Thus, it is not clear that every chemical for which this tentative finding was made would be determined to warrant action under section 5, 6 or 7 upon more comprehensive review.**

More generally, has this provision ever been used and when?

EPA Response: EPA used this provision in 1984 for formaldehyde.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

TSCA TA on animal testing in the manager's amendment version of S.697

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

* * *

~~(5)~~**(3)** by inserting before subsection (f) ~~(as so redesignated)~~ the following:

* * *

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) ~~encouraging and facilitating—~~ **prior to making a request or adopting a requirement for testing using vertebrate animals, taking into consideration, as appropriate and to the extent practicable, reasonably available—**

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

**** 1** "(iii) high-throughput screening methods and the prediction models of those methods; and

**** 2** "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.~~;~~

"(B) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(I) animal-based studies; and

"(II) emerging methods and models; and

~~"(B)~~"(C) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

Commented [GB1]: Although the three preceding references are to "animals" generally, I assume we would undertake these activities only to the extent they related to testing of vertebrates, since these commands fall under the general command in (c)(1) to take steps to minimize use of vertebrates.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

"(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

"(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

Commented [GB2]: Innocuous, in view of more specific language in text.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

"(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

"(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

"(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).

Commented [GB3]: The two highlighted references below seem more likely to be substantive than the preceding references to "animals", since the text seems to flatly ban new animal testing without first having tried to develop info using nonanimal methods that EPA has sanctioned. That said: 1. It's not our problem but industry's, since (B)(i) makes clear that this provision imposes no obligation on EPA; and 2. Since the entire subsection is titled "reduction of testing on vertebrates", there might be an argument that this provision should be limited to vertebrate testing despite its plain language.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 01, 2016 7:08 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Market TSCA TA request- Senate section 5

Michal - this responds to your request on sect 5. Please let me know if any questions. Thanks,
Sven

The proviso under discussion is unnecessary. A section 5 consent agreement generally does not impose testing requirements. See the sample at: http://www.epa.gov/sites/production/files/2016-01/documents/co_all_purpose_preamble_and_consent_order_combined_1-5-2016.pdf at page 6. The order imposes restrictions on the manufacturing, processing, distribution in commerce, use, and disposal of a chemical substance, which continue until such time as EPA receives particular test data. If manufacture never commences in the first place, then there would generally be no testing obligations under the consent agreement. In the event that testing obligations *were* directly incorporated into a section 5 consent agreement, the parties to the agreement would not need statutory authorization to negotiate mutually agreeable terms for the termination of such testing obligations (in the event that manufacture never commences), as part of the original development of the consent agreement.The proviso under discussion could also be harmful. It would entitle a prospective manufacturer to renegotiate or litigate the terms of an existing consent agreement at any point prior to the commencement of manufacture, simply by withdrawing the PMN that was the basis for the consent agreement and then resubmitting the PMN for a fresh 90-day review. Consent agreements would not provide the same assurance of repose for EPA, at least until such time as EPA had made the key terms of the consent agreement generally binding by incorporating them into a Significant New Use Rule.

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 29, 2016 at 2:24:31 PM ES
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TA request- Senate section 5

Sven
Last week I asked you what would happen to a test order/consent agreement under section 5 in the event that a PMN was withdrawn, and your response was that there would be no reason for it to continue in effect and EPA had authority to withdraw it.

The same question has now arisen about an instance in which EPA has entered into a section 5 consent agreement with the PMN submitter and the submitter then withdraws the PMN before submitting a NOC. The question is whether to add a "cease in effect" provision to capture both the section 4 and the section 5 consent agreement scenarios. Is there any circumstance EPA can think of that would make it wish to keep a section 5 consent agreement in effect on a PMN submitter even after the PMN is withdrawn?

Pasting the relevant language below in case it is helpful.
Michal

> (e) Notice of Commencement.—
>
> (1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

(A) the name of the manufacturer; and
(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice. A consent agreement or order issued pursuant to Section 4 [and subsection (d)(3)(A)(i)(I)] shall cease to have legal effect on the date the notice is withdrawn.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

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202-224-2742

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, March 16, 2016 1:13 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey Request on Revised section 14
Attachments: Comprehensive TA on Senate Sec 14 - March 16.docx; ATT00001.htm; 03-15-16PMTSCA - Bicam , EPA.docx; ATT00002.htm

Michal,
Attached is our TA on the new text you asked us to review. Also attached is our remaining TA on section 14, with respect to issues not affected by the new text. Note that we have added a couple of comments not in the last version of section 14 we sent you, which we have picked up on during this latest review.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 7:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 14

Sven

Thanks very much for all your rapid assistance today! Attached is a new draft of section 14. Not all changes have been agreed to among Senate offices – some are being discussed or proposed by us, some are raised by the House, etc. But this is at a stage where we would like EPA TA with an eye for concerns related to workability, possible unintended consequences, drafting concerns, inconsistencies, etc. Fast turnaround appreciated.

Thank you

michal

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~.

"(7) **Specific** aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"~~(7)~~"(8) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if~~—

"~~(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g).~~

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.**—

Commented [A1]: As we have previously pointed out, the reference to subsection (a) appears to make (b) completely inoperative. It says that the listed items are generally CBI, but only to the extent that they would be CBI under ordinary FOIA law – a finding EPA would presumably have to make before (b) is triggered. What does this paragraph add to ordinary FOIA law? In addition, this may increase the number of CBI claims EPA must review, since EPA may not be able treat information as falling under (b) and hence not subject to review without first determining it is CBI.

Commented [A2]: As we have previously pointed out, this proviso for *presumptive* CBI suggests that other CBI will be shielded from discovery, etc.

"(1) IN GENERAL.—**Notwithstanding** subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~"**(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~"**(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of~~ **clause (ii)**—

~~"(i)~~"**(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~"**(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~"**(bb)** any chemical substance or mixture for which—

~~"(aa)~~"**(AA)** testing is required under section 4; or

~~"(bb)~~"**(BB)** a notification is required under section 5; or

~~"(ii)~~"**(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~"**(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

~~"(i)~~"**(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

~~"(ii)~~"**(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

~~"(3)~~"**(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~"**(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

~~"(B)~~"**(ii)** A safety assessment developed, or a safety determination made, under section 6.

Commented [A3]: As we have previously pointed out, this adds nothing and could create confusion, since the point it makes for specific chem id is true for all information – ie, it cannot be CBI if not properly claimed.

~~"(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

~~"(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

~~"(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** **4** ~~"(2)~~**"(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the

performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify:

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency

medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or no longer qualifies for protection against disclosure under subsection (a)**, in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required**

under subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall.~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)**—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d)~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to

a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(4), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

Commented [A4]: This may be very difficult to do logistically. Note that the provision is not limited to information received under TSCA. Consider adding "to the extent feasible".

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

Commented [A5]: This specifies three bases on which information claimed CBI might be released, but misses an important basis: where EPA determines protection is not warranted at some point during the protection period.

Commented [A6]: Certified mail is a cumbersome form of notification.

"(B) RELEASE OF INFORMATION.—**Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator

~~pursuant to subsection (e)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(5) ~~ADMINISTRATION.—IN CARRYING OUT THIS SUBSECTION, THE ADMINISTRATOR SHALL~~

Commented [A7]: Note that this provision applies to information released under (e), as well as information released based on an EPA determination that it is not CBI. Thus, release to first responders, Congress, etc., can be held up by the filing of an appeal. Is that intended? If not, this could be addressed in various ways (e.g., by adding in the intro to (e) "Notwithstanding paragraph (g)(3)(B) of this section. . . ."

~~USE THE PROCEDURES DESCRIBED IN PART 2 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims

Commented [A8]: This provision is confusing. The "information" in question would already have been submitted to EPA, so how would EPA be able to determine the format and language of the information? Also, subsection (g) already provides the timeframes for release of the info, so what more would EPA do to allow for expedient and swift access?

as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 14. CONFIDENTIAL INFORMATION~~DISCLOSURE OF DATA~~.

(a) IN GENERAL.—Except as otherwise provided in ~~by sub~~this section ~~(b)~~, the Administrator shall not disclose ~~any~~ information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

(1) that is reported to, or otherwise obtained by, the Administrator ~~(or any representative of the Administrator)~~ under this Act~~, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information~~; and

(2) for which the requirements of subsection (d) are met.

(b) Information Generally Protected from Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(2) Marketing and sales information.

(3) Information identifying a supplier or customer.

(4) Details of the full composition of a mixture and the respective percentages of constituents.

(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

(6) Specific production or import volumes of the manufacturer.

(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

(8) ~~Except as otherwise provided in this section, t~~The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

(c) Information Not Protected From Disclosure.—

(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:

(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

(i) IN GENERAL.—Subject to clause (ii)—

(I) any health and safety study that is submitted under this Act with respect to—

(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

Commented [A1]: Obsolete citation. There are others in this section, which we have not marked.

Commented [A2]: Per TA provided on 3/15, this "subject to paragraph (2)" addition could give rise to issues, which would be significantly exacerbated by the proposed change to (2), per comments below.

(bb) any chemical substance or mixture for which—

(AA) testing is required under section 4; or

(BB) a notification is required under section 5; or

(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(ii) A ~~safety assessment developed, or a safety determination made~~ risk evaluation conducted under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with or contained in information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

(3) BAN OR PHASE-OUT.—(A) If the Administrator promulgates a rule pursuant to section 6(ad) that establishes a ban or phase-out of ~~the manufacture, processing, or distribution in commerce of~~ a chemical substance, ~~subject to paragraphs (2), (3), and (4) of subsection (g),~~ disclosure of any information protected~~ion~~ from disclosure ~~provided~~ under this section with respect to the ~~specific identity of the particular~~ chemical substance ~~and other information relating to the chemical substance shall no longer apply~~shall be presumed to be in the public interest, subject to ~~a review of a request to maintain protections under~~ subsections (g)(1) (g)(2) and (g)(3).

(BA) EXCEPTIONS FROM PRESUMPTION

(i) Paragraph (3)(A) shall not apply to ~~if thea~~ chemical

Commented [A3]: This addition creates issues. Paragraph (1) identifies information that is not protected from disclosure. While such information can be *submitted with* protectable information, it is hard to see how it can *contain* protectable information. For example, (1)(A) provides, with certain limitations, that health and safety studies are not protected from disclosure. In general, information contained in a health and safety study would be *part of* the health and safety study. If the new language is read to say that any information in a health and safety study that would otherwise be protectable under section 14 remains protected, then that would drain (1)(A) of any force, since the point of (1)(A) (and to some extent the items in(1) (B)) is to require release of information that would otherwise be protectable.

Commented [A4]: This will not provide for release of the information, because nothing in the bill as revised authorizes EPA to release CBI on the grounds that EPA believes the release is in the public interest. In contrast, S 697 provided that protection "shall no longer apply".

substance or particulara conditions of use of thea chemicals substance arefor which an exemption under section 6(g) has been granted exempted from regulation under 6(g);

(ii) For a ban or phase-out of a chemical substance that is not established for all conditions of use of the chemical substance, paragraph (3)(A) shall apply only to information about the chemical substance that relates solely to the conditions of use for which the ban or phase-out is established if the chemical substance is banned or phased out only for particular uses, the presumption shall only apply to claims solely related to the specific uses subject to the ban or phase out;

(iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured solely for export, consistent with section 12; orand

(iv) Paragraph (3)(A) shall apply to for a chemical substance that is subject to a phase out at such time as the , the presumption shall not apply until such time as the phase out is fully implemented.

(3)(4) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is subject to disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

(d) Requirements for Confidentiality Claims.—

(1) ASSERTION OF CLAIMS.—

(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

(i) be consistent with guidance issued by the Administrator under paragraph (3)(A); and

(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

(I) that are considered to be confidential; and

Commented [A5]: This could be read to void the presumption for any information related to the chemical if an exemption is granted for any uses.

Commented [A6]: We are not sure what this would do, but it is confusing. It appears to just say that section 12 (12(a), presumably) governs, which is unnecessary because it governs on its own terms. Also, section 12(a) refers to manufacturing, processing and distribution. Is there a reason this provision applies only to manufacture?

(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and consistent with the guidance issued by the Administrator.

(3) GUIDANCE.—The Administrator shall develop guidance regarding—

(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are true and correct.

(e) Exceptions to Protection from Disclosure.— ~~Information~~ Notwithstanding paragraph (g)(3)(B) of this section, information described in subsection (a)—

(1) shall be disclosed ~~if the information is to shall be disclosed~~ to an ~~any~~ officer or employee of the United States—

(A) in connection with the official duties of that person—

(A) ~~such officer or employee~~ under any law for the protection of human health or the environment; ~~or~~

(B)

(B) for a specific law enforcement purposes;

(2) shall be disclosed ~~if the information is to shall be disclosed~~ to a contractors ~~of with~~ the United States and employees of that ~~such~~ contractors if—

(A) if, in the opinion of the Administrator, the ~~such~~ disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States ~~entered into on or after the date of enactment of this Act~~ for the performance of work in connection with this Act; and

(B) subject to ~~under~~ such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines that disclosure ~~it~~ is necessary to protect health or the ~~environmenenvironment~~ against an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factorst ~~against an unreasonable risk of injury to health or the environment~~;

(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, or tribal government, on written request, for the purpose of development, administration, or enforcement of a law, if 1 or more applicable agreements with the Administrator that are consistent with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the

Commented [A7]: Why added here? TSCA generally refers to health, not human health. Compare (e)(3) below, which just uses "health".

Administrator to safeguard the information and penalties comparable to those under this Act for wrongful disclosure of the information;

(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

(A) the statement of need and confidentiality agreement are consistent with the guidance issued under subsection (d)(3)(B);

(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

(i) the information is necessary for, or will assist in—

(I) the diagnosis or treatment of 1 or more individuals; or

(II) responding to an environmental release or exposure; and

(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

(i) a medical or public health or environmental emergency exists;

(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

(i) provide a written statement of need; and

(ii) agree to sign a confidentiality agreement; and

(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

(74) may be disclosed if the Administrator determines that disclosure is relevant ~~may be disclosed when relevant~~ in ~~any~~ a proceeding under this Act, subject to the condition ~~except~~ that the

Commented [A8]: This added language does not work grammatically

disclosure is ~~in such a proceeding shall be~~ made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding.;

(8) Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee ~~shall be disclosed if the information is to be disclosed, on written request of any duly authorized committee of the Congress, to that committee; or~~

(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

~~In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.~~

(f) Duration of Protection from Disclosure—

(1) IN GENERAL.—

~~(A)~~ DURATION OF PROTECTION FROM DISCLOSURE~~INFORMATION NOT SUBJECT TO TIME LIMIT FOR~~

(B)(A) PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), ~~T~~the Administrator shall protect from disclosure;

(i) information described in subsection (b) that meets the requirements of subsections (a) and (d).; and

~~(ii)~~ for a period of 10 years ,information other than information described in subsection(b) that meets the requirements of subsections(a) and (d) ~~unless~~,

unless

(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

~~(iii)~~(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)~~(2)~~.

~~(C) INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—~~

~~(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or~~

~~(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).~~

~~(D)~~(B) EXTENSIONS.—

(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (B), the Administrator shall provide to the person that asserted

Commented [A9]: The addition of this intro language, for (e)(8) only, may cause confusion, or generate arguments that the release standard for the other 8 items in (e) is more demanding than for this item. We recognize that this language is in TSCA currently only for Congressional release, but that appears to because Congressional release is addressed by its own subsection (14(e)), rather than in 14(a) where the other categories of releasable information are addressed; it therefore arguably needed the "Notwithstanding" language.

Commented [A10]: Per our 3/15 TA, the deletion of this language could create arguments that information that is subject to release under section 14 is nonetheless protectable under FOIA, which could largely drain the section 14 release provisions of any force.

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Commented [A11]: Number is off. This is the second (i).

the claim a notice of the impending expiration of the period.

(ii) STATEMENT.—

(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (d)(2), the need to extend the period.

(II) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—

(aa) review the request submitted under subclause (I);

(bb) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant criteria established under this section; and

(cc)(AA) grant an extension of 10 years; or

(BB) deny the request.

~~(E)~~(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (C), if the Administrator determines that the relevant request under subparagraph (C)(ii)(I)—

(i) establishes the need to extend the period; and

(ii) meets the requirements established by the Administrator.

(2) REVIEW AND RESUBSTANTIATION.—

(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection of information against disclosure under subsection (a) and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

(i) after the chemical substance is identified as a high-priority substance under section 6(b);

(ii) for any chemical substance the Administrator determines in accordance with subsection (b)(4)(A) presents an unreasonable risk of injury to health or the environment~~for which the Administrator has made a determination under section 6(c)(1)(C)~~;

(iii) for any inactive chemical substance identified under section 8(b)(5)(B); or

(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in ~~conducting safety assessments and safety determinations~~risk evaluations under section 6(b) ~~subsections (b) and (c) of section 6~~ or promulgating rules pursuant to section 6(ad).

(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information against disclosure under subsection (a) and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

Commented [A12]: Needs to add 6 (6(b)(4)(A))

Commented [A13]: Should retain "conducting"

(i) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of title 5, United States Code;

(ii) if the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a); or

(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

(i) reassert and substantiate or resubstantiate the claim; or

(ii) withdraw the claim.

(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

(3) UNIQUE IDENTIFIER.—The Administrator shall—

(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

(i) is made public; and

(ii) identifies the chemical substance using the unique identifier; and

(D) for each claim for protection of specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

(g) Duties of Administrator.—

(1) DETERMINATION.—

(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), or receipt of a request to maintain protection of information subject to (c)(3), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, approve in part, or deny the claim or request.

(B) REASONS FOR DENIAL.—If the Administrator denies or denies in part a claim or request under subparagraph (A), the Administrator shall provide to the person that submitted the claim or request a written statement of the reasons for the denial or denial in part of the claim or request.

(C) SUBSETS.— The Administrator shall—

(i) except for claims described in subsection (b)(8), review all claims or requests under this section for the protection against disclosure of the specific identity of a chemical substance; and

(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection against disclosure.

(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim or request for protection against disclosure.

(2) NOTIFICATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e) and (f), if the Administrator denies or denies in part a claim or request under paragraph (1), intends to release information pursuant to subsection (e), or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

(B) RELEASE OF INFORMATION.—Except as provided in subparagraph (C), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

(C) EXCEPTIONS.—

(i) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim or request receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

(I) for the disclosure of information under paragraph (1), (2), (7), or (9) of subsection (e); or

(II) for the disclosure of information for which—

(aa) a notice under subsection (f)(1)(C)(i) was received; and

(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

~~(3) REBUTTABLE PRESUMPTION.—~~

~~(A) IN GENERAL.—With respect to notifications provided by the Administrator under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or a phase-out of the manufacture, processing, or distribution in commerce of the substance, as described in subsection (c)(3), there shall be a~~

rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released pursuant to paragraph (2)(B), a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

(C) DETERMINATION BY ADMINISTRATOR.—

(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed

~~OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.~~

~~(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.~~

~~(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released pursuant to paragraph (2)(B), a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.~~

(4)(3) APPEALS.—

(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released pursuant to paragraph (2)(B), the person may bring an action to restrain disclosure of the information in—

(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

(ii) the United States District Court for the District of Columbia.

(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

~~(5)~~(4) REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.

(~~h~~d) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

(A~~1~~) IN GENERAL.—Subject to paragraph (2), ~~Any~~ a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both~~, or former officer or employee of the United States, who~~

(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

(I) by virtue of that ~~such~~ employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and

(B) who knowing that disclosure of that ~~such~~ material is prohibited by ~~such~~ subsection (a), willfully disclos~~ures~~ the material in any manner to any person not entitled to receive that material~~it~~.

~~shall be guilty of a misdemeanor and fined not more than $5,000 or imprisoned for not more than one year, or both.~~

(2) OTHER LAWS.—Section 1905 of title 18, United States Code, ~~does~~ shall not apply with respect to the publishing, divulging, disclosure, ~~or~~ making known of, or making available, information reported or otherwise obtained under this Act.

(~~3~~2) CONTRACTORS.—For the purposes of this subsection~~paragraph (1)~~, any contractor with the United States that ~~who~~ is provided ~~furnished~~ information in accordance with ~~as authorized by~~ subsection (~~e~~a)(2), including ~~and~~ any employee of that ~~any such~~ contractor, shall be considered to be an employee of the United States.

(i) APPLICABILITY.—

(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable federal law, the Administrator shall have no authority—

(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information reported to or otherwise obtained by the Administrator prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

(2) ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, approving in part or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

~~(b) DATA FROM HEALTH AND SAFETY STUDIES.—(1) Subsection (a) does not prohibit the disclosure of—~~

~~(A) any health and safety study which is submitted under this Act with respect to—~~

~~(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or~~

~~(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and~~

~~(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).~~

~~This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.~~

~~(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the~~

Commented [A14]: We don't see the inconsistency and note that this provision is in current TSCA. Without this, arguments may be raised that section 1905 provides for broader protection than section 14. Because this provision has been in TSCA from its inception, removing the provision would create confusion as to the applicability of section 14 vs. the Trade Secrets Act.

Commented [A15]: Previously, "under this Act" appeared after "Administrator". Why removed? The revised version bars substantiation for information received under other EPA statutes.

~~Administrator may not deny such request on the basis of subsection (b)(4) of such section.~~

~~(c) DESIGNATION AND RELEASE OF CONFIDENTIAL DATA.—(1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.~~

~~(2)(A) Except as provided by subparagraph (B), if the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of 30 days after the manufacturer, processor, or distributor in commerce submitting such data has received the notice required by this subparagraph.~~

~~(B)(i) Subparagraph (A) shall not apply to the release of information under paragraph (1), (2), (3), or (4) of subsection (a), except that the Administrator may not release data under paragraph (3) of subsection (a) unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.~~

~~(ii) Subparagraph (A) shall not apply to the release of information described in subsection (b)(1) other than information described in the second sentence of such subsection.~~

~~(e) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.~~

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, March 30, 2016 8:26 AM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Sen. Markey TSCA Inquiry on Section 14(f)(2)(A)(iv)

Michal,

This TA responds to the request on section 14(f)(2)(A)(iv).

Question: If [Section 14(f)(2)(A)(iv)] was deleted, would EPA still retain its discretionary authority to review CBI claims in the manner it currently does (ie, the example given in past TA was when disclosure of CBI might be useful to get better public comments on proposed rules etc)? Would EPA be able to, for example, review a. CBI claim of a company making a chemical substitute for a chemical EPA was planning to ban, in order to get more information about that substitute during the rulemaking process?

Response: EPA believes the deletion of Section 14(f)(2)(A)(iv) has the potential to impair EPA's authority to disclose information claimed as CBI as part of development of a rule. This potential impairment would arise largely from the decision to delete the provision from the Senate bill as passed, since it would likely be argued that that decision was intended to have some effect.

Had the provision never been in the Senate bill, we do not think its absence would significantly impair EPA's authority to disclose information claimed as CBI as part of development of a rule, for two reasons:

1. Although section 14(f)(2)(A) identifies situations in which EPA "may" *review* CBI claims, section 14(i) limits EPA's authority only with respect to imposing *substantiation or re-substantiation* requirements. Thus, EPA would likely take the position that the list of bases for review in section 14(a)(2)(A) is not exclusive, and that EPA has inherent authority to conduct internal reviews of CBI claims. (Again, such an argument would be undercut if (iv) were dropped from section 14(a)(2)(A), unless the deletion were accompanied by a very clear explanatory statement in the conference report that acknowledges that EPA already has general authority to review CBI claims, even without 14(f)(2)(A)(iv), and that Congress simply removed redundant verbiage.)

2. Even if Section 14(f)(2)(A)(iv) limits EPA's authority to review claims, section 14(e)(7) of the bill authorizes EPA to disclose CBI where "relevant in a proceeding under the Act". Although EPA would be required to preserve confidentiality to the maximum extent practicable without impairing the proceeding, EPA would have discretion to determine how much disclosure is needed to avoid impairing the proceeding.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 24, 2016 12:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 14(f)(2)(A)(iv)

Sven

If this was deleted, would EPA still retain its discretionary authority to review CBI claims in the manner it currently does (ie, the example given in past TA was when disclosure of CBI might be useful to get better public comments on proposed rules etc)? Would EPA be able to, for example, review a. CBI claim of a company making a chemical substitute for a chemical EPA was planning to ban, in order to get more information about that substitute during the rulemaking process?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 24, 2016 5:38 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA request - section 9
Attachments: Markey.TSCA TA.Section 9b Public Interest.docx

Michal,
This responds to your TA request on section 9 on public interest determinations. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, February 19, 2016 7:00 PM
To: Kaiser, Sven-Erik
Subject: TA request - section 9

Not for the weekend.
has EPA ever made a public interest determination under section 9? If so, could you describe details?
House Section 9 requires EPA to do a cost-benefit analysis of another federal agency regulating a chemical substance before making a public interest determination. Would EPA be able to properly do an analysis like this on statutes it doesn't administer? Are there any operational or workability concerns EPA has with the language?
Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

[H]as EPA ever made a public interest determination under section 9? If so, could you describe details?

Yes, in 1988 EPA determined that it was in the public interest to use TSCA rather than the CAA to address certain risks of hexavalent chromium (even though "TSCA and the CAA could require equally stringent control limitations.") 53 FR 10206 (March 29, 1988). The rationale was that TSCA provided a better mechanism for enforcement, since requirements could apply to distributors and vendors instead of individual cooling towers.

In a 1991 proposal, EPA determined that it was in the public interest to use TSCA rather than the CWA or RCRA to address certain risks of dioxins in paper mill sludge. 56 FR 21802 (May 10, 1991). EPA determined that TSCA requirements could be more specifically tailored than RCRA requirements and that they could be more comprehensive in scope than CWA requirements.

In other circumstances, EPA has indicated that it is disinclined to make such a public interest determination. For example: respecting the use of TSCA rather than the Ocean Dumping Act to address PCB contamination from sunken Naval vessels, 77 FR 42183-4 (July 18, 2012); or respecting the use of TSCA rather than the Clean Air Act to address ocean acidification from anthropogenic carbon dioxide. 80 FR 60581-2 (October 7, 2015).

1. *House Section 9 requires EPA to do a cost-benefit analysis of another federal agency regulating a chemical substance before making a public interest determination. Would EPA be able to properly do an analysis like this on statutes it doesn't administer? Are there any operational or workability concerns EPA has with the language?*

The House bill does not substantively amend section 9(a), regarding referral to another Agency, so the premise of the question is mistaken.

The House bill amends section 9(b), respecting the public interest finding that EPA must make to manage a risk under TSCA if it has initially determined that risk management actions under "other Federal laws administered in whole or in part by the Administrator" would be sufficient to address the risk. The public interest finding is "in the Administrator's discretion," and legislative history reflects the view of the conferees that the outcome finding was not substantively reviewable in court. H.R. 94-1679 at 85 (1976). The conferees indicated that a court could still address EPA's failure to conduct the necessary analysis prior to making a public interest finding.

The analytical requirements that the House bill attaches to section 9(b) are similar to the status quo under TSCA. Note, however, that the analytical requirements for 9(b) are currently located in section 6(c):

> "If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may

> not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury." TSCA § 6(c).

The House bill's section 9(b)(2) tracks and relocates the pertinent passage from current section 6(c). EPA has two drafting observations:

- House 9(b)(2) discusses taking "an action" under TSCA "rather than under another law administered in whole or in part by the Administrator." If the objective is simply to maintain the current structure of TSCA section 9, this should be changed to a discussion of "action**s**" taken under TSCA "rather than under another law **(or laws).**" Here's why:
  - Current 6(c) operates in the plural: it refers to "actions under this Act" and non-TSCA "law (or laws)" that EPA administers.
  - For purposes of intra-agency coordination under current 9(b), the threshold finding is based on the sufficiency of actions under the non-TSCA authorities that the Administrator has charge over.
  - This highlights a different approach taken under 9(a), for purposes of inter-agency referral. In section 9(a), the threshold finding is based on the sufficiency of action under a single non-EPA Federal law.
- House 9(b)(2) directs EPA to "consider the relevant risks." Compare with current TSCA 6(c): "consider . . . all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion."
  - It is unclear whether 9(b)(2) is an enlargement or an expansion of the finding requirements under 6(c):
    - "all relevant aspects of the risk" has been changed to "the relevant risks"
    - Mention of the Administrator having discretion to identify the scope of the risks was deleted.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 22, 2016 3:19 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA - another 6(a) alternative

Michal,
This TA responds to the request to review a 6(a) option dealing with section 18 and (c)(2) references.

> OPTION 2
> (a) SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

The changes you suggest do help address the specific issue we identified in our most recent TA -- the suggestion that section 18 and 6(c)(2) are on the same footing as limitations on EPA's authority. However, it does not address our long standing point that we think the reference to section 18 in this context is unnecessary and confusing. We understand your point about addressing Geier, but we think section 18 already does that (and if it doesn't, it's hard to see how a reference to it in section 6 would). The reference to section 18 in section 6(c) of the offer indicates that EPA's *authority* to promulgate rules under section 6(c) is limited in some way by section 18, which we do not understand to be your intent. Presumably, you mean to say that the *preemptive effect* of any rules EPA promulgates under section 6(c) is subject to section 18. (And, again, we don't really see the value of making such a point in section 6, since section 18 already provides that it governs the preemptive effect of section 6 rules, and has whatever effect it has with respect to Geier.)

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 21, 2016 12:17 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: another 6(a) alternative

OPTION 2

(a) SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, February 23, 2016 5:24 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA - redrafted section 5
Attachments: Markey.TSCA TA.Section 5 text received on February 22.docx

Michal – the attached TA responds to your request, including the additional 5(d) question. We highlighted the more significant comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 22, 2016 3:51 PM
To: Kaiser, Sven-Erik
Subject: section 5

Sven

I'm attaching a re-draft of section 5, with some streamlining and other more substantive changes. I'd appreciate your team's take, with a particular focus on the areas where we shifted away from a 'safety standard' and back to an 'unreasonable risk' construct, and to anything else you think could pose workability or other challenges.

I'd appreciate getting this back before 11 AM tomorrow and hope that is doable.

Thanks
Michal

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SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.~~MANUFACTURING AND PROCESSING NOTICES.~~

(a) DEFINITION.—For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(ba) ~~NOTICES IN GENERAL.~~—(1) Except as provided in paragraph (3) and subsection (~~h~~g), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (c)~~(d)~~, of such person's intention to manufacture or process such substance ~~and such person complies with any applicable requirement of subsection (b)~~.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) ARTICLE CONSIDERATION.—The Administrator may require the notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.

Commented [A1]: EPA: "The" had been deleted from the senate draft.

(c) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—

Commented [A2]: All streamlining and conforming changes

(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

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(B) all known or reasonably ascertainable information regarding conditions of use and reasonably anticipated exposures.

(2) Subject to section 14, at the beginning of each month, the Administrator shall publish in the Federal Register—

(A) a list identifying, by generic class unless the Administrator determines that more specific information is required in the public interest, each chemical substance for which notice has been received under subsection (b), along with the conditions of use for each such substance, and for which the notification period prescribed by subsection (b) or (d) has not expired; and

(B) a list identifying each chemical substance for which such notification period has expired since the last publication of such list.

~~(b) SUBMISSION OF TEST DATA.—(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a)(1).~~

~~(B) If—~~

~~(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and~~

~~(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule promulgated under section 4 before the submission of such notice,~~

~~such person may not, before the expiration of the 90-day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).~~

~~(2)(A) If a person—~~

~~(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and~~

~~(ii) is not required by a rule promulgated under section 4 before the submission of such notice to submit test data for such substance,~~

~~such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).~~

~~(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that—~~

~~(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture,~~

Commented [A3]: EPA: Add "identified in the notice"?

Commented [A4]: EPA: Probably makes more sense to substitute "the review period prescribed by subsection (d)", since it's the review period, not the notification period, that seems to govern completion of review.

Commented [A5]: EPA: Again, review period would probably be better.

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~~processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or~~

~~(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.~~

~~(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.~~

~~(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.~~

~~(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—~~

~~(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and~~

~~(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.~~

~~(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.~~

~~(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).~~

~~(c) EXTENSION OF NOTICE PERIOD. The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.~~

(d) Review of Notice.—

Commented [A6]: All streamlining

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(1) INITIAL REVIEW.—

(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall, following a review of the notice and any relevant information about the chemical substance available to the Administrator, including information about the potential for exposure to humans and the environment and any relevant information identified in subsection (c)(1), make a determination under paragraph (2).

(B) EXTENSION.—Except as provided in paragraph (2)(C), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall not be more than 90 days.

(23) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and subject to section 18(g), the Administrator shall—

A) determine, without a consideration of costs or other non-risk factors, that the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment under the conditions of use to the general population or to a potentially exposed or susceptible population identified by the Administrator, in which case the Administrator shall take applicable action under paragraph (3);

(B) determine that manufacture of the chemical substance or manufacture and processing of the chemical substance for the significant new use may commence, notwithstanding any remaining portion of the applicable period for review under subsection (b)(1); or

(C) determine that additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator—

(i) shall provide an opportunity for the submitter of the notice to submit the information, and may extend the review period for a reasonable amount of time by agreement with the submitter to allow the development and submission of the information;

(ii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

(iii) shall, on receipt of information the Administrator finds sufficient to support a determination under subparagraph (A) or (B), promptly make the determination, and take action under paragraph (3) as applicable.

(3) RESTRICTIONS.—

(A) DETERMINATION BY THE ADMINISTRATOR.—

(i) IN GENERAL.—If the Administrator makes a determination under paragraph (2)(A) with respect to a notice submitted under subsection (b) —

Commented [A7]: EPA: Should be "reasonably available"?

Commented [A8]: EPA: This is redundant, since this this information in the "notice", which is already referenced above.

Commented [A9]: EPA: In response to the specific TA request of 12:09pm, February 23, about reviewability in court:

The determination seems to meet the Bennet v. Spear test for a final agency action. It marks the culmination of a decision-making process established under § 5(d)(2) and legal consequences flow from the decision. This would be reviewable in court under the APA, subject to a 6-year statute of limitations. It is not covered under TSCA Section 19 (Judicial Review) but the main effect of that fact is to send judicial review to a U.S. District Court under the 6-year limit, not the Courts of Appeals under the TSCA 60-day limit.

Commented [A10]: Another option for review and discussion

Commented [A11]: EPA: It is confusing to say that EPA's determination is subject to the preemption provisions. Presumably the intent is to say something about the *effects* of an EPA determination (and even that would be confusing and unnecessary).

Commented [A12]: EPA: Note that, while EPA does not view this as a very high bar, there is some caselaw indicating that the standard requires EPA to find an overlap between levels of concern and actual exposure.

Commented [A13]: EPA: This contains no standard for the decision. Without clarification, this could lead to litigation about whether or not a (d)(2)(B) determination impliedly requires showing that a (d)(2)(A) determination is impossible. If that is the intended objective, you could say something like "determines that there is no [reasonable?] basis to determine that the chemical substance may present. . . ."

Commented [A14]: EPA:

1.Nothing prevents manufacture in the meantime for these chemicals. Is that intentional? If the data comes back 2 years later showing that the chemical may present an unreasonable risk, it does not appear that a determination under (2)(A) or a restriction under (3) would be timely. Both provisions seem to assume that action is occurring within the ordinary review period of 90-180 days.

2.In line with the comment above as to the "may present" standard, "(C)" may indicate that EPA needs a fairly substantial amount of information to make the "may present" finding in "(A)". Under current TSCA, EPA can make the "may present" finding for new chemicals only where "information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects" of the chemical substance. In contrast, the drafting here suggests that lack of information would be a reason *not* to make a "may present" finding.

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(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, such that the Administrator determines that compliance with such prohibition or restrictions are sufficient to ensure that there is no longer a reasonable basis to conclude that the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment; and

(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the consent agreement or order, and, as applicable, initiate such a rulemaking, or publish a statement describing the reasons by the Administrator for not initiating such a rulemaking.

(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include any requirement or combination of requirements listed in section 6(a).

(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that there is no longer a reasonable basis to determine that the chemical substance may present an unreasonable risk to health and the environment, reduce potential exposure to the substance to the maximum extent practicable.

Commented [A15]: EPA: Distribution in commerce and use are reversed form usual order.

Commented [A16]: EPA: Should be "is"

Commented [A17]: EPA: Not part of the (2)(A) standard, but may be as good a formulation as any.

Commented [A18]: EPA: Note that this bars any person (not just the submitter) from activity that would be inconsistent with the order or agreement. In contrast, under TSCA currently, a section 5(e) order restricts only the recipient. The bill formulation calls into question the need for EPA to considering issuing a SNUR, as would be required by subparagraph (B), since the purpose of a SNUR following a 5(e) order is typically to apply the terms of the order to persons who are not parties to the order.. This is an issue with the current Senate bill drafting that we had not picked up on before.

Commented [A19]: EPA: "such a" would be better

Commented [A20]: EPA: Should be "of"?

Commented [A21]: x-ref as discussed, but note that EPA says it doesn't need any list at all.

Commented [A22]: EPA: Note that the current 6(a) list is not comprehensive.

Commented [A23]: EPA: "Reasonable basis" is not in the standard (but again my not be a bad formulation).

Commented [A24]: EPA: Should add "of injury" after "risk"

Commented [A25]: EPA: Should be "or"

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(E) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

Commented [A26]: EPA: Makes no sense – how would a term displace common law? And the section generally uses "restriction" not "requirement" anyway.

(e) Notice of Commencement.—

(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

(A) the name of the manufacturer; and

(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

(f) Further evaluation.—The Administrator may review a chemical substance for which a notice of commencement has been submitted at any time, consistent with Section 6. .

~~(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—(1) The notice required by subsection (a) shall include—~~

~~(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and~~

~~(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and~~

~~(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.~~

~~Such a notice shall be made available, subject to section 14, for examination by interested persons.~~

~~(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which—~~

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(A) identifies the chemical substance for which notice or data has been received;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) or a rule under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—

(1)(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the

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date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,

the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency,

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issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.

(3)(A) The Administrator may—

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the

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~~District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.~~

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.~~

~~(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A), and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).~~

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.~~

~~(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.~~

(g) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection ~~(a) or~~ (b) to

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permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, without taking into account cost or other non-risk factors, and

(B) under such restrictions as the Administrator considers appropriate.

~~(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—~~

~~(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2), and~~

~~(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,~~

~~the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.~~

~~(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—~~

~~(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b) (2) to submit such data, and~~

~~(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.~~

~~In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the~~

~~Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to~~

~~provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.~~

~~(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—~~

~~(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and~~

~~(ii) ending—~~

~~(I) five years after the date referred to in clause (i), or~~

~~(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,~~

~~whichever is later.~~

(2~~3~~) The requirements of subsections ~~(a) and~~ (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(3~~4~~) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines, without a consideration of costs and other non-risk factors, that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator. ~~A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).~~

(4~~5~~) The Administrator may, upon application, make the requirements of subsections ~~(a) and~~ (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical

Commented [A27]: EPA: Drop "a"

Commented [A28]: EPA: Should be "cost or", not "costs and".

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substance, and (B) to which there is no, and will not be, human or environmental exposure.

(5~~6~~) Immediately upon receipt of an application under paragraph (1) or (4)~~(5)~~ the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

~~(i) DEFINITION.—For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.~~

[15 U.S.C. 2604]

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 29, 2016 6:01 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA - section 5 restrictions and inclusions
Attachments: Markey.TSCA TA.Section 5 Restrictions and Inclusions.docx

Michal,
The attached technical assistance responds to your request on section 5 restrictions and inclusions.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 5:51 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TSCA TA - redrafted section 5

For starters:

On the question of restrictions under section 5 – there is a desire by some to maintain the existing 697 list of restrictions rather than cross-referencing the 6(a) list, which as you point out is itself also more narrow than current authority. Can you point to times EPA has taken action related to a new chemical that it would not be able to take under S 697 as reported? What about under the 6(a)list?

michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.~~MANUFACTURING AND PROCESSING NOTICES.~~

(a) DEFINITION.—For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(b~~a~~)-NOTICES~~IN GENERAL~~.—(1) Except as provided in paragraph (3) and subsection (~~h~~g), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (c)~~(d)~~, of such person's intention to manufacture or process such substance ~~and such person complies with any applicable requirement of subsection (b)~~.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) ARTICLE CONSIDERATION.—The Administrator may require the notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.

Commented [A1]: EPA: "The" had been deleted from the senate draft.

(c) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—

Commented [A2]: All streamlining and conforming changes

(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

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(B) all known or reasonably ascertainable information regarding conditions of use and reasonably anticipated exposures.

(2) Subject to section 14, at the beginning of each month, the Administrator shall publish in the Federal Register—

(A) a list identifying, by generic class unless the Administrator determines that more specific information is required in the public interest, each chemical substance for which notice has been received under subsection (b), along with the conditions of use for each such substance, and for which the notification period prescribed by subsection (b) or (d) has not expired; and

(B) a list identifying each chemical substance for which such notification period has expired since the last publication of such list.

~~(b) SUBMISSION OF TEST DATA.—(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a)(1).~~

~~(B) If—~~

~~(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and~~

~~(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule promulgated under section 4 before the submission of such notice,~~

~~such person may not, before the expiration of the 90-day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).~~

~~(2)(A) If a person—~~

~~(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and~~

~~(ii) is not required by a rule promulgated under section 4 before the submission of such notice to submit test data for such substance,~~

~~such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).~~

~~(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that—~~

~~(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture,~~

Commented [A3]: EPA: Add "identified in the notice"?

Commented [A4]: EPA: Probably makes more sense to substitute "the review period prescribed by subsection (d)", since it's the review period, not the notification period, that seems to govern completion of review.

Commented [A5]: EPA: Again, review period would probably be better.

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~~processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or~~

~~(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.~~

~~(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.~~

~~(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.~~

~~(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—~~

~~(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and~~

~~(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.~~

~~(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.~~

~~(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).~~

~~(c) EXTENSION OF NOTICE PERIOD. The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.~~

(d) Review of Notice.—

Commented [A6]: All streamlining

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(1) INITIAL REVIEW.—

(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall, following a review of the notice and any relevant information about the chemical substance available to the Administrator, including information about the potential for exposure to humans and the environment and any relevant information identified in subsection (c)(1), make a determination under paragraph (2). =

(B) EXTENSION.—Except as provided in paragraph (2)(C), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall not be more than 90 days.

(23) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and subject to section 18(g), the Administrator shall—

A) determine, without a consideration of costs or other non-risk factors, that the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment under the conditions of use to the general population or to a potentially exposed or susceptible population identified by the Administrator, in which case the Administrator shall take applicable action under paragraph (3);

(B) determine that manufacture of the chemical substance or manufacture and processing of the chemical substance for the significant new use may commence, notwithstanding any remaining portion of the applicable period for review under subsection (b)(1); or

(C) determine that additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator—

(i) shall provide an opportunity for the submitter of the notice to submit the information, and may extend the review period for a reasonable amount of time by agreement with the submitter to allow the development and submission of the information;

(ii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

(iii) shall, on receipt of information the Administrator finds sufficient to support a determination under subparagraph (A) or (B), promptly make the determination, and take action under paragraph (3) as applicable.

(3) RESTRICTIONS.—

(A) DETERMINATION BY THE ADMINISTRATOR.—

(i) IN GENERAL.—If the Administrator makes a determination under paragraph (2)(A) with respect to a notice submitted under subsection (b) —

Commented [A7]: EPA: Should be "reasonably available"?

Commented [A8]: EPA: This is redundant, since this this information in the "notice", which is already referenced above.

Commented [A9]: EPA: In response to the specific TA request of 12:09pm, February 23, about reviewability in court:

The determination seems to meet the Bennet v. Spear test for a final agency action. It marks the culmination of a decision-making process established under § 5(d)(2) and legal consequences flow from the decision. This would be reviewable in court under the APA, subject to a 6-year statute of limitations. It is not covered under TSCA Section 19 (Judicial Review) but the main effect of that fact is to send judicial review to a U.S. District Court under the 6-year limit, not the Courts of Appeals under the TSCA 60-day limit.

Commented [A10]: Another option for review and discussion

Commented [A11]: EPA: It is confusing to say that EPA's determination is subject to the preemption provisions. Presumably the intent is to say something about the *effects* of an EPA determination (and even that would be confusing and unnecessary).

Commented [A12]: EPA: Note that, while EPA does not view this as a very high bar, there is some caselaw indicating that the standard requires EPA to find an overlap between levels of concern and actual exposure.

Commented [A13]: EPA: This contains no standard for the decision. Without clarification, this could lead to litigation about whether or not a (d)(2)(B) determination impliedly requires showing that a (d)(2)(A) determination is impossible. If that is the intended objective, you could say something like "determines that there is no [reasonable?] basis to determine that the chemical substance may present. . . ."

Commented [A14]: EPA:

1.Nothing prevents manufacture in the meantime for these chemicals. Is that intentional? If the data comes back 2 years later showing that the chemical may present an unreasonable risk, it does not appear that a determination under (2)(A) or a restriction under (3) would be timely. Both provisions seem to assume that action is occurring within the ordinary review period of 90-180 days.

2.In line with the comment above as to the "may present" standard, "(C)" may indicate that EPA needs a fairly substantial amount of information to make the "may present" finding in "(A)". Under current TSCA, EPA can make the "may present" finding for new chemicals only where "information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects" of the chemical substance. In contrast, the drafting here suggests that lack of information would be a reason *not* to make a "may present" finding.

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(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, such that the Administrator determines that compliance with such prohibition or restrictions are sufficient to ensure that there is no longer a reasonable basis to conclude that the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment; and

(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the consent agreement or order, and, as applicable, initiate such a rulemaking, or publish a statement describing the reasons by the Administrator for not initiating such a rulemaking.

(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include any requirement or combination of requirements listed in section 6(a).

(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that there is no longer a reasonable basis to determine that the chemical substance may present an unreasonable risk to health and the environment, reduce potential exposure to the substance to the maximum extent practicable.

Commented [A15]: EPA: Distribution in commerce and use are reversed form usual order.

Commented [A16]: EPA: Should be "is"

Commented [A17]: EPA: Not part of the (2)(A) standard, but may be as good a formulation as any.

Commented [A18]: EPA: Note that this bars any person (not just the submitter) from activity that would be inconsistent with the order or agreement. In contrast, under TSCA currently, a section 5(e) order restricts only the recipient. The bill formulation calls into question the need for EPA to considering issuing a SNUR, as would be required by subparagraph (B), since the purpose of a SNUR following a 5(e) order is typically to apply the terms of the order to persons who are not parties to the order.. This is an issue with the current Senate bill drafting that we had not picked up on before.

Commented [A19]: EPA: "such a" would be better

Commented [A20]: EPA: Should be "of"?

Commented [A21]: x-ref as discussed, but note that EPA says it doesn't need any list at all.

Commented [A22]: EPA: Note that the current 6(a) list is not comprehensive.

Commented [A23]: EPA: "Reasonable basis" is not in the standard (but again my not be a bad formulation).

Commented [A24]: EPA: Should add "of injury" after "risk"

Commented [A25]: EPA: Should be "or"

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(E) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

Commented [A26]: EPA: Makes no sense – how would a term displace common law? And the section generally uses "restriction" not "requirement" anyway.

(e) Notice of Commencement.—

(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

(A) the name of the manufacturer; and

(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

(f) Further evaluation.—The Administrator may review a chemical substance for which a notice of commencement has been submitted at any time, consistent with Section 6. .

~~(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—(1) The notice required by subsection (a) shall include—~~

~~(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and~~

~~(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and~~

~~(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.~~

~~Such a notice shall be made available, subject to section 14, for examination by interested persons.~~

~~(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which—~~

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(A) identifies the chemical substance for which notice or data has been received;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) or a rule under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—

(1)(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the

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date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,

the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency,

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issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.

(3)(A) The Administrator may—

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the

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~~District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.~~

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.~~

~~(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).~~

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.~~

~~(g) STATEMENT OF REASONS FOR NOT TAKING ACTION. If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.~~

(g) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection ~~(a) or~~ (b) to

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permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, without taking into account cost or other non-risk factors, and

(B) under such restrictions as the Administrator considers appropriate.

~~(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—~~

~~(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2), and~~

~~(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,~~

~~the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.~~

~~(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—~~

~~(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b) (2) to submit such data, and~~

~~(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.~~

~~In promulgating rules for the determination of fair and equitable~~ reimbursement to the persons described in clauses (i) and (ii) for ~~costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the~~

~~Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to~~

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~~provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.~~

~~(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—~~

~~(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and~~

~~(ii) ending—~~

~~(I) five years after the date referred to in clause (i), or~~

~~(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,~~

~~whichever is later.~~

(2) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(3) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines, without a consideration of costs and other non-risk factors, that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).

Commented [A27]: EPA: Drop "a"

Commented [A28]: EPA: Should be "cost or", not "costs and".

(4) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical

substance, and (B) to which there is no, and will not be, human or environmental exposure.

(5~~6~~) Immediately upon receipt of an application under paragraph (1) or (4)(~~5~~) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

~~(i) DEFINITION.—For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.~~

[15 U.S.C. 2604]

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 10, 2016 10:12 AM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA - Senate section 4

Michal,
In response to your request, please see EPA's TA below. The add on request from last night will follow separately. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

a) Could EPA test under these 5 scenarios under the Senate bill absent a high priority designation? Would Senate (4)(a)(2) be enough to do all these things?

Your question assumes that the chemical substance has not been designated as a high priority.

We note, however, that Scenarios 3 and 4 seem to relate to the selection of risk management options. Such scenarios would follow from a prior safety determination, which would follow from a prior high priority designation. In that case, EPA would have broad authority to require testing to support the safety assessment and determination.

In all Scenarios, Section 4(a)(1)(D) provides clear authority for EPA to require testing if the EPA testing action is in response to a request from a government authority operating under a non-TSCA federal law. This would include requests from other operating units of EPA that are not charged with implementing TSCA, but have separate legal authorities to address the scenario at issue.

In Scenarios 1, 2 and 5, Section 4(a)(2) provides a viable authority to require testing. EPA would probably need to list the chemical substance in question as 'under consideration' for prioritization in order to justify the testing requirement. It also appears that upon receipt of the requested test data, EPA would be obliged, within 90 days, to either designate the chemical substance as a high priority for a safety assessment or a low priority.

b) Has EPA required testing in the past for the 5 scenarios?

1) **If a chemical about which little was known spilled into drinking water, could EPA require testing?** At the request of the Office of Water, on November 10, 1993, OPPT published a final TSCA Section 4 Test Rule (58 FR 59667) covering four chemicals of interest to the Office of Drinking Water (ODW). The chemicals subject to this rule (chloroethane, 1,3,5-trimethylbenzene, 1,1-dichloroethane, and 1,1,2,2-tetrachloroethane) were unregulated drinking water contaminants for which ODW needed data in order to develop 1-day, 10-day, and long term/lifetime health advisories. The required testing included

14- and 90-day oral toxicity studies in rats on each of the subject chemicals. The final rule discusses the value of establishing health advisories to provide guidance to officials responsible for protecting health after chemical spills.

2) **If there was a cancer cluster in a particular community and a suspected chemical connection, could EPA test that chemical?**

No test rule addressing this scenario has been issued.

3) **If there was a group of chemicals used in widely distributed consumer products but insufficient toxicology data, could EPA do testing to figure out what needed to go on the warning** label etc?
No test rule addressing this scenario has been issued.

4) **If there was a suspected workplace exposure, could EPA test to see what sort of occupational control measures were needed?**
This was done in the "OSHA Dermal Test Rule"; In Vitro Dermal Absorption Rate Testing of Certain Chemicals of Interest to the Occupational Safety and Health Administration. 69 FR 22402; April 26, 2004. OSHA needed quantitative measures of dermal absorption to evaluate the potential hazard of these chemicals to workers and to justify the "Skin" notation in OSHA's 29 CFR 1910.1000 standard which required the use of gloves or other equipment to protect the skin, and the test rule was issued to require the development of such data.

5) **What about a class of chemicals like flame retardants, where EPA wants to do testing on different compounds in the class?**
OPPT entered into an Enforceable Consent Agreement (ECA) for incineration testing of four formulated composites of fluoropolymer chemicals. The four formulations were "representative of all known commercial FP chemicals." OPPT wanted to find out if the FP chemicals degraded into PFOA, because of developmental toxicity, carcinogenicity, and blood monitoring data concerns associated with PFOA (70 FR 39630; 07/08/05).

Additionally, the neurotoxicity endpoint rule required the neurotoxicity testing of 7 organic solvents for neurotoxicity due to the neurological effects seen in painters due to "solvent syndrome."(NPRM: 56 FR 9105, March 4, 1991; NFRM: 58 FR 59667, Nov 10, 1993; Revocation: 60 FR 4514, Jan 23, 1995; Testing Consent Orders for Acetone, N-Amyl Acetate, N-Butyl Acetate, Ethyl acetate, Isobutyl Alcohol, Methyl Isobutyl Ketone, and Tetrahydrofuran: 60 FR 4516, Jan 23, 1995).

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, February 04, 2016 6:21 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - Senate section 4

Sven

In reviewing Senate section 4, some have raised concerns with Senate 4(a) and indeed, have said that Senate 4(a) is more restrictive than the retention of the TSCA 4(a) 'unreasonable risk' finding that needs to be made before testing can occur on some chemicals.

I'm pasting the language below, and then following that with some questions based on the concerns I've recently heard:

(a) Development of New Information on Chemical Substances and Mixtures.—

(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

(C) pursuant to section 12(a)(4); or

(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

QUESTIONS:

1) If a chemical about which little was known spilled into drinking water, could EPA require testing?
2) If there was a cancer cluster in a particular community and a suspected chemical connection, could EPA test that chemical?
3) If there was a group of chemicals used in widely distributed consumer products but insufficient toxicology data, could EPA do testing to figure out what needed to go on the warning label etc?
4) If there was a suspected workplace exposure, could EPA test to see what sort of occupational control measures were needed?
5) What about a class of chemicals like flame retardants, where EPA wants to do testing on different compounds in the class?

Basically all these examples relate to existing chemicals, not new chemicals, and the view is that unless EPA puts them all into a high priority listing, it could not really get this data under Senate 4(a)(1). So my questions are generally, a) could EPA test under these sorts of scenarios under the Senate bill absent a high priority designation? Would Senate (4)(a)(2) be enough to do all these things? and b) has EPA required testing in the past for these sorts of scenarios?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 3:24 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal,
This TA responds to your request on the alternate formulation. Explicitly tying disclosure regarding a ban or phaseout to "a request to maintain protections under subsections (g)(1) (g)(2) and (g)(3)" could be read to indicate that EPA can't make such information public until after the Agency receives a request from the company to maintain protection for the information. This seems unlikely to be the result that you intended.

In addition, Your draft language cites to (g)(1), (g)(2) and (g)(3), whereas the relevant provision in the Senate bill and offer cite to (g)(2), (g)(3) and (g)(4). We do not think citation to (g)(1) of the Senate bill or offer would make sense. If the intent is to cite to (2) through (4) of the Senate bill and offer, we think that would make sense (although, as stated above, we do not think the addition of reference to "request" makes sense).

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 17, 2016 12:27 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Another formulation

> (1) BAN OR PHASE-OUT.—(A) If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any information under this section with respect to the chemical substance shall be presumed to no longer apply, subject to a review of a request to maintain protections under subsections (g)(1) (g)(2) and (g)(3).

Michal Ilana Freedhoff, Ph.D.
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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 16, 2016 7:00 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it-checking along with the last one. Thanks,
Sven

On Mar 16, 2016, at 6:46 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does this work for 14(c)(3)(B)

> (B) EXCEPTIONS FROM PRESUMPTION
> (i) Paragraph (3)(A) shall not apply to any condition of use of a chemical substance for which an exemption under section 6(g) has been granted;
> (ii) For a ban or phase-out of a chemical substance that is not established for all conditions of use of the chemical substance, paragraph (3)(A) shall apply only to information about the chemical substance that relates solely to the conditions of use for which the ban or phase-out is established ;
> (iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured, processed and distributed solely for export if EPA determines that section 12(a)(1) shall not apply to the chemical substance in accordance with section 12(a)(2). [MF1]; and
> (iv) Paragraph (3)(A) shall apply to a chemical substance that is subject to a phase out at such time as the phase out is fully implemented.

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202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 4:43 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

Please let me know if any additional questions. Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 1:16 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

(c) Information Not Protected From Disclosure.—
(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:
(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
(i) IN GENERAL.—Subject to clause (ii)—
(I) any health and safety study that is submitted under this Act with respect to—
(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or.
(bb) any chemical substance or mixture for which—
(AA) testing is required under section 4; or
(BB) a notification is required under section 5; or
(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).
(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—
(I) a process used in the manufacturing or processing of a chemical substance or mixture; or
(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.
(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:
(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(ii) A safety assessment developed, or a safety determination made, under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 1:13 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,
This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 10:32 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)